EPA Test Guidelines
(Office of Toxic Substances)

Includes:

- o Toxic Substances: Test Rule Development and Exemption Procedures: Final Rule (10/10/84)
- o Enforcement Response Policy for Test Rules under Section 4 of the Toxic Substances Control Act (5/28/86)
- o Polyhalogenated Dibenzo-p-Dioxins/Dibenzofurans: Testing and Reporting Requirements: Final Rule (6/5/87)
- o Alternative Methodology for Acute Toxicity Testing (9/22/88)

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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

CONVERSION TABLE—Continued

Proposed rule Part 770	Section title	Final rule Part 790
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

§ 790.60 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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Enforcement Response
Policy for Test Rules. . .

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

MEMORANDUM

MAY 28 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Enforcement Response Policy
for TSCA §4 Test Rules

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

TO: Addressees

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

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

Attachments

MAY 28 1986

ENFORCEMENT RESPONSE POLICY

FOR TEST RULES UNDER

SECTION 4 OF THE

TOXIC SUBSTANCES CONTROL ACT

OFFICE OF COMPLIANCE MONITORING

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ENFORCEMENT RESPONSE POLICY FOR TSCA §4 TEST RULES

TSCA SECTION 4 TEST RULES

ENFORCEMENT RESPONSE POLICY

OVERVIEW

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

APPLICABILITY

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

LEVELS OF ACTION

NOTICES OF NONCOMPLIANCE (NON)

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

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

CIVIL PENALTIES

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

CRIMINAL SANCTIONS

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

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

ASSESSMENT OF CIVIL PENALTIES

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

GRAVITY-BASED PENALTY MATRIX

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

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

NATURE

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

EXTENT

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

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

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

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

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

CIRCUMSTANCES

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

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

Level 1

(1) Falsification of submitted data.

(2) Failure to test.

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

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

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

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

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

Level 3

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

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

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

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

Level 4

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

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

Level 5

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

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

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

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

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

Level 6

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

CONTINUING VIOLATIONS

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

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

(1) Falsification of data.

(2) Failure to test.

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

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

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

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

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

MULTIPLE VIOLATIONS

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

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

ADJUSTMENT FACTORS

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

1. Voluntary Disclosure

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

2. Immediate Voluntary Disclosure

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

3. Gains from Noncompliance

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

- Hazard Assessment only

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

* Subject to Continuing Day Assessment + Subject to Multiple Violation factor

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

Polyhalogenated Dibenzo-p-
Dioxins/Dibenzofurans: Testin

federal register

Friday
June 5, 1987

Part II

Environmental Protection Agency

40 CFR Parts 707 and 766
Polyhalogenated Dibenzo-p-Dioxins/ Dibenzofurans; Testing and Reporting Requirements; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 707 and 766

[OPTS-83002C; FRL-3212-1]

Polyhalogenated Dibenzo-p-Dioxins/ Dibenzofurans; Testing and Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document promulgates regulations under sections 4 and 8 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603 and 2607 for certain chemicals which may be contaminated with certain chlorinated and brominated dibenzo-p-dioxins (HDDs) and dibenzofurans (HDFs). HHDs and HDFs have been recognized as having potential public health and environmental significance because of their potential for industrial toxic effect at very low doses. The regulations promulgated under this document require analytical testing for certain chemicals for HDD/HDF contamination, submission of existing test data on contamination of these chemicals with HDDs/HDFs, submission of health and safety studies on HDDs/HDFs, and submission of worker allegations of significant adverse reactions to HDDs/HDFs. A summary of the requirements of this rule is set forth under **SUPPLEMENTARY INFORMATION**, below.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern standard time on June 19, 1987. This rule shall be effective on July 6, 1987.

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

SUPPLEMENTARY INFORMATION: This rule requires manufacturers and importers of 12 organic chemicals to test their chemicals for the presence of certain chlorinated and brominated dibenzo-p-dioxins and dibenzofurans. This testing will also be required for 20 additional organic chemicals not currently manufactured or imported in the United States if their manufacture or importation should resume.

Manufacturers, importers, and processors of the 12 chemicals must also submit existing test data on contamination of these chemicals with HDDs or HDFs, health and safety studies on HDDs/HDFs, and consumer or worker allegations of significant adverse reactions to HDDs/HDFs; the same information on the 20 additional chemicals is required should manufacture or importation resume.

If either the testing required under this rule, or the existing test data on contamination submitted under this rule show that any of these chemicals contain any HDDs/HDFs in concentrations above the Levels of Quantitation (LOQ) designated in this rule, the manufacturers and/or importers must submit the following information with respect to the chemicals: (1) Production volume, process, use, exposure, and disposal data; (2) unpublished health and safety studies, and (3) records of allegations of significant adverse reactions.

This rule also requires the submission of process and reaction condition data by importers and manufacturers of chemical substances made from any of 29 precursor chemicals to determine whether there is a need for dioxin and furan testing of the chemical substances made from these precursor chemicals.

If testing of a chemical under this rule shows the chemical does not contain HDDs/HDFs, this rule provides for termination of export notification normally required under section 12(b) of TSCA, 15 U.S.C. 2611(b), for a chemical subject to section 4 test rules.

I. Organization of this Final Rule

This is a final rule issued after consideration of comments submitted in response to a proposed rule published in the **Federal Register** of December 19, 1985 (50 FR 51794), an amendment to the proposed rule published in the **Federal Register** of October 23, 1986 (51 FR 37612), and all relevant information submitted to or otherwise obtained by EPA.

The preamble to this final rule begins with the historical background (Unit II), and continues with a short summary of changes from the provisions proposed (Unit III). Unit IV discusses findings and considerations under section 4 of TSCA; Unit V discusses costs of testing and reporting; and Unit VI discusses the availability of testing facilities and personnel to perform the proposed testing. Unit VII discusses EPA's rationale for issuing information gathering rules under section 8 of TSCA. Unit VIII discusses the relationship of this rule to export notification requirements under section 12(b) of TSCA; Unit IX discusses compliance and enforcement; Unit X describes the rulemaking record; and Unit XI lists references used by EPA in preparing this rule. Requirements EPA must meet under other authorities before it may issue a rule are discussed in Unit XII.

II. Background

A. Regulation of HDDs/HDFs

EPA has long recognized the potential public health and environmental significance of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). 2,3,7,8-TCDD exhibits delayed biological response in many species and is lethal at exceptionally low doses to aquatic organisms, birds, and some mammals. It has been shown to be carcinogenic, teratogenic, fetotoxic, and acnegenic. In addition, 2,3,7,8-TCDD has been shown to adversely affect the immune response in mammals. EPA also recognizes the potential health significance of a variety of tetra- through hepta-halogenated dibenzo-p-dioxins and dibenzofurans (HDDs and HDFs) that are structurally related to 2,3,7,8-TCDD in that they are chlorinated or brominated at the 2,3,7 and 8 positions on the molecular structure (Refs. 5 and 15). Limited *in vivo* and *in vitro* data support the structure-activity based argument that laterally substituted 2,3,7,8-HDDs/HDFs share qualitative toxicity properties with 2,3,7,8-TCDD. There is also evidence that 2,3,7,8-TCDD, some of the other HDDs/HDFs and by implication the remainder of th HDDs/HDFs may be hazardous to human health and the environment at low levels. These 2,3,7,8-substituted tetra- through hepta- dibenzo-p-dioxins and dibenzofurans, as well as 2,3,7,8-TCDD, are the subjects of this rulemaking. Hereafter, unless otherwise stated, this document will refer to tetra- through hepta- chlorinated and brominated dioxins and dibenzofurans substituted at the 2,3,7 and 8 positions as a group by using the term "HDDs/HDFs." The 2,3,7,8-HDDs/HDFs have been measured in a number of commercial chemicals (Ref. 43). EPA has reason to believe that they also appear in a number of other commercial chemicals which are structurally similar to those in which HDDs/HDFs have been measured, and are manufactured under conditions favorable to HDD/HDF formation.

EPA's National Dioxin Strategy (Ref. 32), issued in December 1983, offers a comprehensive overview of EPA's past, present, and planned activities in this area. EPA's past regulatory efforts on HDDs/HDFs focused on a number of products and processes that could generate HDDs and HDFs or could otherwise lead to human or environmental exposure to these substances. These activities were note

in the preamble to the proposed rule under Unit I. Since that time EPA has taken the following additional actions: (1) A final agreement between EPA and manufacturers of wood preserving products containing pentachlorophenol, subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was reached regarding analysis and maximum permissible limits in pentachlorophenol for HDDs; (2) treatment standards under the Resource Conservation and Recovery Act (RCRA) for dioxin-containing hazardous waste were proposed January 14, 1986 (51 FR 1602), and promulgated November 7, 1986 (51 FR 40572, 40615); (3) cancellation of the dioxin-contaminated herbicides 2,4,5-T and silvex were completed in February 1985; (4) a notice of intent to cancel most non-wood preservative registrations of pentachlorophenol was published on January 21, 1987 (52 FR 2282); (5) a Dioxin Update Committee (Ref. 40) of scientific experts was convened to determine their views in the areas of human health effects, immunotoxicity, bioavailability, mechanism of action and appropriate risk assessment procedures for 2,3,7,8-TCDD; and (6) a favorable review was issued by the Science Advisory Board of the application of Toxicity Equivalency factors developed by Drs. Barnes and Bellin to estimate the toxicity of congeners of HDDs/HDFs other than 2,3,7,8-TCDD (Ref. 35). In addition, the following regulatory activities are underway within EPA to control or eliminate potential human or environmental exposure to HDDs/HDFs: RCRA listing of HDDs/HDFs as "acutely hazardous" wastes; RCRA land ban disposal rule; evaluation of waste streams from pentachlorophenol wood treaters; municipal waste combustion guidelines and evaluation of ash residues from municipal combustion; establishment of National Pollutant Discharge Effluent Standards (NPDES) discharge limits, and numerous Superfund site cleanup activities.

B. Background to This Final Rule

On October 22, 1984, the Environmental Defense Fund and the National Wildlife Federation filed a citizens' petition under section 21 of TSCA, 15 U.S.C. 2620. The petition (Ref. 14) requested that EPA commence certain regulatory actions related to certain HDDs and HDFs and initiate related investigations and research.

More specifically, the petitioners asked EPA to use its authority under TSCA to analyze aggregate hazards posed by multi-media releases of the specific HDDs/HDFs subject to this rule (those substituted at the 2,3,7 and 8 positions on the benzene rings) and to take action under TSCA to commence an integrated, multi-media effort to reduce the risks from the release of these chemicals.

Although the petitioners acknowledged that EPA in its Dioxin Strategy (Ref. 32) has recognized the need for a multi-media approach in cleaning up contamination, they believe that EPA has not taken sufficient action to prevent future contamination from the continued generation of HDDs and HDFs as contaminants during the manufacture of other chemicals and materials. The petitioners requested that EPA take a number of specific regulatory and information-gathering steps under TSCA to regulate the HDDs/HDFs generically, as a class of chemicals.

EPA decided that, in general, it would deny the request to regulate the specified HDDs/HDFs under a multi-media TSCA approach for two reasons: (1) The Agency was already proceeding to gather extensive data and initiate regulation under other, more appropriate statutes, and (2) EPA did not have the data needed to make a finding of unreasonable risk under section 6 of TSCA, the provision of the Act that authorizes substantive regulation of chemicals. EPA did decide, however, to grant part of the petition and on December 19, 1985 (50 FR 51794) proposed this rulemaking under sections 4 and 8 of TSCA to gather additional information on HDDs/HDFs in commercial chemicals. EPA will review the data submitted as a result of this rule to decide whether additional regulatory action under section 6 of TSCA is warranted to limit or control the further manufacture, processing, distribution in commerce, and/or use of chemicals contaminated with HDDs/HDFs.

EPA received 13 comments to the proposed rule during the public comment period, which closed on February 18, 1986. On March 4, 1986, EPA held a public hearing in Washington, DC where three organizations presented testimony. A transcript of this meeting is in the public docket file for this rule. EPA also held a meeting closed to the public on March 4, 1986, at the request of Great Lakes Chemical Co. (Great Lakes), to receive confidential business information (CBI) from Great Lakes and to request additional CBI on listed chemicals manufactured by the company. A transcript of the meeting and a copy of letters in which EPA requested specific data are included in the rulemaking record for this rule. A second public meeting was held April 22, 1986, in Washington, DC, at the request of the Chemical Manufacturers' Association (CMA), to allow CMA to present the Agency with a proposal for an alternative procedure for collecting the needed data. This procedure and EPA's evaluation of it are discussed under Unit IV of this preamble.

As a result of comments made at these meetings and other information received by EPA, the Agency amended the proposed rule and solicited public views and data on whether to collect process and reaction condition data on 18 additional chlorinated and brominated benzenes under section 8(a) of TSCA (51 FR 37612, October 23, 1986). The Agency received five comments to that proposed amendment and responds to those comments in appropriate sections of this preamble.

Also in response to comments, EPA has amended 40 CFR Part 707 to provide for termination of reporting for export purposes under section 12(b) of TSCA when testing shows no contamination of a chemical by HDDs/HDFs above the LOQs.

EPA has considered all the comments received and other relevant information obtained by the Agency, and has modified other parts of the rule appropriately. The comments are addressed under the appropriate sections of this preamble.

EPA believes that production, processing, distribution, use, and disposal of the listed chemicals may present an unreasonable risk of injury to human health and the environment because of their potential for contamination by chlorinated and brominated dibenzo-p-dioxins and dibenzofurans. EPA believes these contaminants may present a health risk at very low levels, down to 0.1 part per billion (ppb) for 2,3,7,8-TCDD, the most toxic congener, and for 2,3,7,8-tetrabromodibenzo-p-dioxin (TBDD), believed to be equally as toxic. Therefore, this target level of quantitation has been set for 2,3,7,8-TCDD and 2,3,7,8-TBDD, with higher levels for the remaining congeners based on toxicity equivalent to that of 2,3,7,8-TCDD. These levels are targets, and EPA expects testing laboratories to make a good faith effort to reach these targets. EPA's Director of the Office of Toxic Substances (OTS) will determine whether good faith efforts are made, advised by a panel of experts in analytical chemistry convened by EPA. In cases where good faith efforts are made, EPA will accept results higher than the target LOQs. EPA also believes

that the differences in cost to test for HDDs/HDF at 0.1 ppb or 10 ppb or even 100 ppb are very small because the major part of the cost of testing is incurred by separation of matrix and clean-up of sample, and this cost will be approximately the same for these levels.

III. Comparison of Proposed and Final Rule

A. Testing Requirements Under Section 4

Under section 4 of TSCA, explained in the proposed rule under Unit II.B., EPA proposed to require testing of 14 currently manufactured or imported chemicals and 20 chemicals not currently manufactured or imported. In this rule, EPA is requiring testing for HDD/HDF contamination of 12 currently manufactured or imported chemicals, and 20 chemicals not currently manufactured or imported if their manufacture or importation resumes. The two chemicals removed from the list are 2,4-Dichlorophenoxyacetic acid and 2,4-Dichlorophenoxybutyric acid, chemicals which are both pesticides and pesticide intermediates. Contamination of these two chemicals by HDDs/HDFs will be determined by a Data Call-In Program conducted under FIFRA. The 12 chemicals, which are subject to testing as of the promulgation date of this rule, are listed below with their Chemical Abstract Services (CAS) registry numbers.

CAS No.	Chemical name
79-94-7	Tetrabromobisphenol-A.
118-75-2	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione.
118-79-6	2,4,6-Tribromophenol.
120-83-2	2,4-Dichlorophenol.
1163-19-5	Decabromodiphenyloxide.
4162-45-2	Tetrabromobisphenol-A-bisethoxylate.
21850-44-2	Tetrabromobisphenol-A-bis-2,3-dibromopropylether.
25327-89-3	Allyl ether of tetrabromobisphenol-A.
32534-81-9	Pentabromodiphenyloxide.
32536-52-0	Octabromodiphenyloxide.
37853-59-1	1,2-Bis(tribromophenoxy)-ethane.
55205-38-4	Tetrabromobisphenol-A diacrylate.

(EPA has assumed that a chemical is currently manufactured if it was manufactured since January 1, 1984.)

The 20 chemicals, which will be subject to testing after their manufacture or importation resumes, are listed below.

CAS No.	Chemical name
79-95-8	Tetrachlorobisphenol-A.
87-10-5	3,4',5-Tribromosalicylanilide.
87-65-0	2,6 Dichlorophenol.
95-77-2	3,4-Dichlorophenol.
95-95-4	2,4,5-Trichlorophenol.
99-28-5	2,6-Dibromo-4-nitrophenol.
120-36-5	2[2,4-(Dichlorophenoxy)]-propanoic acid.
320-72-9	3,5-Dichlorosalicyclic acid.
488-47-1	Tetrabromocatechol.
576-24-9	2,3-Dichlorophenol.
583-78-8	2,5-Dichlorophenol.
608-71-9	Pentabromophenol.
615-58-7	2,4-Dibromophenol.
933-75-5	2,3,6-Trichlorophenol.
1940-42-7	4-Bromo-2,5-dichlorophenol.
2577-72-2	3,5-Dibromosalicylanilide.
3772-94-9	Pentachlorophenyl laurate.
37853-61-5	Bismethylether of tetrabromobisphenol-A.
.....	Alkylamine tetrachlorophenate.
.....	Tetrabromobisphenol-B.

Manufacturers of any listed chemical may request an exclusion or waiver from testing for any of four reasons: (1) Detailed process and reaction condition data for the chemical show the absence of conditions, conducive to HDD/HDF formation; (2) existing test data on the chemical meet the testing requirements of this rule in terms of Quality Assurance/Quality Control (QA/QC) and best effort to analyze at lowest possible LOQs; (3) an affirmation signed by a responsible company official that the chemical is produced at levels of 100 kilograms per year or less, and is used only for research and development purposes; and (4) the manufacturer provides evidence that the chemical, due to the cost of testing, will either be taken off the market or will not reach the market, and the chemical can be shown to result in no unreasonable risk. This last exclusion/waiver is intended to provide an opportunity for EPA to grant relief from testing requirements in circumstances where the cost of testing would preclude production of a chemical and no unreasonable risk would result if the chemical were produced. Requests for exclusions/waivers must be submitted within 60 days of the effective date of this rule. Persons who plan to resume manufacture, import or processing of a chemical listed for testing must apply for an exclusion 60 days prior to actual such resumption. EPA will issue in the Federal Register a notice of receipt of any requests for exclusion under this rule, and a notice of its decision on each such request.

Persons required to test under this rule must, within 60 days of the effective date, or 60 days after they become subject to the rule, submit to EPA either a letter of intent to test or an application for exemption/waiver. For chlorinated chemicals, persons who submit a notice of intent to test must submit to EPA, within 12 months of such submission, chemical matrix-specific test protocols sensitive enough to quantitate to the target LOQs specified in this rule, or if one or more of those levels are not possible for a given matrix, for the lowest possible level of quantitation achievable. For brominated chemicals, the protocols must be submitted within 24 months of submission of the notice of intent to test. Should testing be required in the future for a chemical in which both chlorine and bromine occur, and neither predominates, testing would be required for both chlorinated and brominated HDDs/HDFs. For a discussion of requirements for such protocols, see Unit IV.B.2. and §§ 766.1 766.12, 766.14, 766.16, and 766.18 of this rule.

LOQs for each congener have been adjusted based on toxic equivalency to 2,3,7,8-TCDD, using the Toxic Equivalency Factors developed by Drs Barnes and Bellin of EPA (Refs. 4 and 35). Using very limited data, and in the absence of data to the contrary, brominated HDDs/HDFs have been assumed to be as toxic as their chlorinated counterparts.

The rule requires that these target LOQs be achieved through the use of high-resolution gas chromatography (HRGC) with high resolution mass spectra detection (HR MS), unless another method can be demonstrated to reach the target LOQs as well or better.

EPA will convene a panel of analytical chemists employed by the U.S. Government and expert in HDD/HDF analysis to review the protocols and offer recommendations where necessary to ensure that the methods are capable of accurately and precisely measuring HDDs/HDFs at the target or the lowest possible levels. During the review process EPA will take into account the possibility that interferences may not allow quantitation to the levels specified and, in those cases where good faith efforts have been made to reach the target LOQ, the Agency may agree to an analytical protocol which results in a higher LOQ. This determination will be made by the Director of the Office of Toxic Substances based on the recommendation of the expert panel.

To facilitate the development of extraction, cleanup, and analysis procedures in these protocols, EPA will provide a guidance document titled, "Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products" (Ref. 24). This guidance document has been adjusted to allow (QA/QC) as follows: the level of reproducibility is plus/minus 20 percent, recovery levels for spiked internal calibration standards are 50 to 150 percent.

Within 6 months of the completion of EPA review of the protocols, test results must be submitted to EPA.

To summarize, as a result of consideration of comments, EPA made some changes from the proposal. The chemicals manufactured both as pesticides and as isolated intermed

of pesticide products, 2,4-Dichlorophenoxyacetic acid and 2,4-Dichlorophenoxybutyric acid, were deleted from the list of chemicals to be tested. LOQs were modified to take into account Toxic Equivalency Factors (TEFs) developed by EPA for the different HDD/HDF congeners. The timeframes for submission of protocols and test results have been modified. QA/QC requirements have been adjusted. Testing for one chemical manufactured by Dow Chemical Company (Dow) has been excluded as a result of comments submitted on the proposed rule. The rule provides procedures whereby companies may present to EPA information that may convince the Agency to exclude their chemicals from testing or waive the testing requirements.

Finally, the regulations under TSCA section 12(b) have been amended to provide termination of reporting for export purposes when data have been submitted showing no HDDs/HDFs present above the LOQs. These changes and the reasons therefor are discussed in the appropriate places later in this preamble.

B. Reporting Requirements Under Section 8

Under section 8(a) of TSCA, EPA may require chemical manufacturers and processors to maintain such records and submit such reports as the Agency may reasonably require. EPA has determined that certain chemical manufacturers must submit information to assist the Agency in evaluating the risk from chemicals potentially contaminated with HDDs/HDFs. The data required to be submitted under section 8 will be used to complete a comprehensive overview of uses, exposures, risks, and advantages of chemicals containing or potentially containing the HDDs/HDFs so that EPA may assess the need for and nature of future regulatory control measures.

This rule requires manufacturers (including importers) and processors of the 12 chemicals listed for testing to submit, 90 days after the effective date of this rule, any available test results, with necessary protocols, which show the results of any existing testing of their chemicals for concentrations of HDDs/HDFs. These test data may also be used to support an exclusion from testing. Persons who manufacture or import any of the 20 chemicals not currently in production must submit this information within 90 days of the resumption of manufacture or importation.

The manufacturers, importers, and processors of the 12 chemicals must also submit, under section 8(c) of TSCA, allegations in their possession of significant adverse reactions to HDDs/HDFs and, under section 8(d) of TSCA, any unpublished health and safety studies they may have on HDDs/HDFs. This information must be submitted to EPA within 90 days from the effective date of this rule, or 90 days after the person begins manufacture or import, whichever is later.

In addition, should the testing conducted under this rule or the existing test data submitted under section 8 of TSCA show that particular chemicals contain HDDs/HDFs above the designated LOQs, the manufacturers (including importers) of those particular chemicals must submit, under section 8(a), production volume, process and reaction conditions, exposure, use and disposal data as specified on EPA Form 7710-51. Submitters may request copies of the form from the TSCA Assistance Office, or submit the data required by the form. In addition, these manufacturers and importers must then submit, under section 8(c) of TSCA, records of alleged adverse reactions to the tested chemicals, and, under section 8(d) of TSCA, unpublished health and safety studies on the tested chemicals. This section 8(a), (c), and (d) information must be submitted 90 days after the submission of a positive test result as defined at § 766.3.

If testing data from this rule show that for a particular chemical, some manufacturers report HDDs/HDFs significantly above the designated LOQs and others show no contamination, EPA may require through publication of a notice in the Federal Register, that all manufacturers and importers of that chemical submit process and reaction condition data. This means that manufacturers who have reported no contamination may be required to supply data.

Finally, under section 8(a) of TSCA, manufacturers (except small manufacturers) of chemicals using any of certain listed precursor chemicals as feedstocks or intermediates must submit data on manufacturing process and reaction conditions for the chemicals they manufacture using these precursors. These precursor chemicals are not themselves contaminated, but can, during further processing and under certain reaction conditions, lead to formation of HDDs/HDFs in other chemicals. Should EPA learn from this data gathering process that reaction conditions favorable to HDD/HDF formation exist, EPA may propose additional chemicals for testing.

The original December 1985 proposal listed 12 precursor chemicals. After considering comments, however, EPA amended the proposal and opened a comment period to accept comments on the addition of 18 chlorinated and brominated benzenes to the list of precursor chemicals.

One of these 18 added chemicals, pentachloronitrobenzene (PCNB), was removed from the list after comments received in response to the proposed amendment showed that this chemical is not currently manufactured in the U.S., is imported only for use as a registered active ingredient (pesticide use only), and as such is regulated under FIFRA. All details concerning manufacturing process, intermediates, reactions and product chemistry for this chemical have been submitted to EPA as required under FIFRA's special Data Call-In letter of May 8, 1985. Because this chemical is not subject to TSCA jurisdiction at this time, it has been deleted. Should EPA receive information indicating that PCNB manufacture or importation resumes for non-pesticidal uses subject to jurisdiction under TSCA, this chemical may again be added to the list of precursors subject to the reporting requirements outlined above. This final rule thus incorporates all 29 chemicals into the precursor list.

The complete list of the 29 precursor chemicals appears below.

CAS No.	Chemical name
85-22-3	Pentabromoethylbenzene.
87-61-6	1,2,3-Trichlorobenzene.
87-84-3	1,2,3,4,5, Pentabromo-6-chlorocyclohexane.
89-61-2	1,4-Dichloro-2-nitrobenzene.
89-64-5	4-Chloro-2-nitrophenol.
89-69-0	2,4,5-Trichloronitrobenzene.
92-04-6	2-Chloro-4-phenylphenol.
94-74-6	4-Chloro-o-toloxy acetic acid.
94-81-5	4-(2-Methyl-4-chlorophenoxy) butryic acid.
95-50-1	o-Dichlorobenzene.
95-56-7	o-Bromophenol.
95-57-8	o-Chlorophenol.
95-88-5	4-Chlororesorcinol.
95-94-3	1,2,4,5-Tetrachlorobenzene.
97-50-7	5-Chloro-2,4-dimethoxyaniline.
99-30-9	2,6-Dichloro-4-nitroaniline.
99-54-7	1,2-Dichloro-4-nitrobenzene.
106-37-6	Dibromobenzene.
106-46-7	p-Dichlorobenzene.
108-70-3	1,3,5-Trichlorobenzene.
108-86-1	Bromobenzene.
108-90-7	Chlorobenzene.
117-18-0	1,2,4,5-Tetrachloro-3-nitrobenzene.
120-82-1	1,2,4-Trichlorobenzene.
348-51-6	o-Chlorofluorobenzene.
350-30-1	3-Chloro-4-fluoronitrobenzene.
615-67-8	Chlorohydroquinone.
626-39-1	1,3,5-Tribromobenzene.
827-94-1	2,6-Dibromo-4-nitroaniline.

EPA made only two changes to reporting requirements under section 8 of TSCA. After considering comments, EPA added the 17 chlorinated and brominated benzenes to the original 12 precursor chemicals. In addition, EPA deleted a number of reporting requirements for chemicals manufactured from the precursors. Specifically, requirements for all data

other than process and reaction conditions have been eliminated. These changes and the reasons therefor are discussed in the appropriate places in this preamble.

IV. Findings and Considerations

A. Findings Under Section 4(a)

Section 4 of TSCA authorizes EPA to require, by rule, that chemical manufacturers or processors conduct tests to develop data relevant to the determination that the chemicals do or do not present an unreasonable risk of injury to health or the environment. EPA must make a number of findings before it may issue a section 4 rule. Under section 4(a)(1)(A), EPA must find that a chemical may present an unreasonable risk of injury to health or the environment, that there are insufficient data and experience upon which the effects of activities involving the chemical can reasonably be determined or predicted, and that testing of the chemical is necessary to develop such data.

EPA makes four findings under section 4(a)(1)(A) of TSCA with respect to the 32 chemicals listed in this final rule. First, EPA finds that these chemicals may present an unreasonable risk of injury to health or the environment because they may be contaminated with HDDs/HDFs, which may be highly toxic even at trace levels. Second, EPA finds that there are insufficient data upon which the effects of these chemicals on health or the environment could reasonably be determined because EPA has very little data on whether there is any HDD/HDF contamination and, if so, the levels of such contamination. Third, EPA finds that analytical testing is necessary to develop data on HDD/HDF contaminant levels because such testing is the only way to determine conclusively whether and at what levels HDDs/HDFs are present. Fourth, EPA finds that this analytical testing is relevant to determining whether activities involving the 32 substances do or do not present an unreasonable risk. Further, EPA finds that the cost of testing for the presence of these contaminants at the levels proposed by EPA is reasonable given the potentially highly toxic nature of these HDDs/HDFs.

In support of these findings, EPA adopts the analysis set forth in the preamble to the proposed rule under Unit IV.A. and V., modified as discussed below. These modifications were made as a result of consideration of comments and other relevant information. Below, EPA discusses the comments received on its proposed findings, and the Agency's response. Discussion of each comment also contains a reference to the person(s) who submitted it.

1. *EPA's legal authority to require analytic testing under section 4 of TSCA—Comment 1:* EPA lacks legal authority under section 4 of TSCA to require analytical testing for impurities in chemicals. Section 4 does not explicitly refer to testing for contamination, but rather limits EPA to requiring testing on "health and environmental effects." Section 4(b)(2)(A) describes the "effects" and "characteristics" for which testing is permitted and does not mention tests for contamination. This position is supported by the legislative history. An early Senate version of TSCA (S. 776 (1975)) contained specific language allowing contaminant testing. That language was left out of the final version of TSCA, thus indicating that Congress did not intend to allow contaminant testing under section 4. (CMA pp. 6–9; Vulcan p. 1).

Response to Comment 1: EPA disagrees with this narrow reading of TSCA. EPA interprets section 4 to allow the testing of chemicals to obtain data relevant to a determination of unreasonable risk. These data include the types of information which would be generated by testing under the proposed rule. EPA rejects the position taken by these commenters, which would limit section 4 to toxicity testing, rather than "effects" testing.

Section 4(a) provides that EPA, after making certain findings, may require testing of a chemical—

> to develop data . . . which are relevant to a determination that . . . [the chemical] does or does not present an unreasonable risk of injury to health or the environment.

Section 4(b)(2)(A) states that the effects for which test standards may be prescribed include a number of specific effects "and any other effect which may present an unreasonable risk of injury to health or the environment." In addition, characteristics for which standards may be prescribed include specific characteristics and "any other characteristic which may present such a[n unreasonable] risk."

The potential for a chemical to be contaminated with dangerous impurities, such as HDDs, falls within the "effects" or "characteristics" of that chemical which would be relevant to whether the chemical may present an unreasonable risk. Requiring analytical testing of the type discussed in the proposed rule— the levels at which a particular toxic contaminant, such as HDDs, is present in a chemical substance—is an important factor in any determination of unreasonable risk because it provides EPA with information from which human and environmental exposure to the contaminant can be assessed. Moreover, information on the amount of the contaminant in a chemical substance allows the Agency to better assess the hazard of that particular chemical substance. Finally, requiring chemical manufacturers to conduct such analytical chemistry testing is consistent with the well-defined Congressional intent in enacting TSCA that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substance and mixtures[.]" TSCA section 2(b)(1).

The fact that section 4 does not specifically mention contaminant testing is not dispositive. The types of tests listed in section 4 are only examples.

Finally, CMA's reference to S. 776 does not support CMA's position. S. 776 provided that, if EPA determines that a chemical may present an unreasonable risk, the Agency shall "prescribe standards for a test protocol for such substance." A test protocol is specifically defined as a method to be followed in tests to "determine the effects of the manufacture, processing, or distribution in commerce of a chemical substance." The bill goes on to state that in prescribing the protocols, EPA:

> shall require that information pertaining to all relevant factors with respect to the applicable chemical substance be developed. Such factors include—
>
> (A) the effects of the substance on human health, and the magnitude of human exposure; and,
>
> (B) the effects of such substance on the environment, and the magnitude of environmental exposure.
>
> (2) Standards for test protocols . . . may require that tests be performed, in accordance with those protocols, for carcinogenicity, mutagenicity, teratogenicity, acute toxicity, subacute toxicity, chronic toxicity, cumulative properties, synergistic properties, clinical effects, epidemiological effects, ecological effects and other effects of such substance which might cause unreasonable risk to human health or the environment.

CMA apparently argues that the language referring to the "magnitude of exposure" was deleted from the final version of TSCA and, thus, supports the position that Congress limited EPA's authority to "effects" testing. CMA cites no further explanation in the legislative

history for the deletion of the "magnitude of exposure" language.

EPA views the legislative history as supportive of its position. Both S. 776 and the final version of TSCA indicate an intention that "relevant" factors be tested. There is an additional parallel between the two versions, indicating they both refer to the same types of testing. S. 776 refers to factors relevant to health effects and magnitude of exposure; TSCA refers to factors relevant to "unreasonable risk." Plainly, unreasonable risk includes elements of toxicity and exposure.

CMA's interpretation of the legislative history, regardless of the effect of deleting the "magnitude of exposure" language, does not affect this rule. Contaminant testing, as noted above, is "effects" testing.

2. *Comments on EPA's approach to this rule—Comment 2:* Before requiring testing under section 4 of TSCA on HDDs/HDFs, EPA should use TSCA section 8(a) authority to collect extensive exposure data, specifically information on production, process, use, and disposal. Only then can EPA determine whether there may be an unreasonable risk requiring testing under section 4(a). This approach (collecting section 8(a) information before proposing section 4 testing rules) is the Agency's standard approach to responding to recommendations for testing chemicals made by the Interagency Testing Committee (ITC) under section 4(e) of TSCA. The Agency could use the SNUR provision to gather information on the chemicals. (CMA at pp. 2–4; Dow at p. 2; Great Lakes at p. 2; pp. 3/4 in comments to proposed amendment adding additional precursor chemicals).

Response to Comment 2: EPA disagrees with this comment. The amount of exposure information needed to test under section 4 of TSCA, which requires a finding that a chemical "may" present an unreasonable risk, need not be as extensive as that needed to regulate under section 6 of TSCA, which requires a finding that a chemical "will" present an unreasonable risk. The comments confuse the type of information and level of detail needed to issue a section 4 testing rule with information needed to issue requirements under section 6 of TSCA.

Furthermore, when EPA has information, as it does for HDDs/HDFs, that a chemical may be highly toxic at very low levels, the amount of exposure data needed to make a section 4(a) finding may be even less definitive. For HDDs/HDFs the major uncertainties are their presence and levels of concentration in commercial chemicals. If HDDs/HDFs are present, even at low levels, the toxicity of that chemical may be high based on the impurity.

In addition, EPA believes that it would be counterproductive to obtain section 8(a) exposure data on chemicals potentially contaminated with HDDs/HDFs if testing shows that these contaminants are in fact not present. This would also delay the Agency's ability to concentrate its attention on those chemicals contaminated and to determine whether regulation to reduce exposure is necessary. Only if contamination is present above the LOQs will EPA collect the detailed process, reaction condition, production, use, exposure, and disposal data to determine whether the chemical does in fact present an unreasonable risk of harm to human health or the environment.

Finally, EPA disagrees with the suggestion that, instead of section 4 testing rules, SNURs under section 5(a) of TSCA should be used to gather information on particular uses of the chemicals subject to this rule. EPA believes the logic behind this comment is reversed. Doing a SNUR before testing these chemicals would only prolong the regulatory process unnecessarily. The Agency should first gather general information on HDD/HDF levels in the manufactured chemical and then consider whether particular downstream uses should be subject to regulatory requirements. At that point, EPA could decide such issues as whether potential downstream uses should be subject to SNURs or whether substantive regulatory requirements under section 6 of TSCA should be promulgated. Further, gathering information on specific uses first would be counterproductive, since it is a useless exercise to promulgate a SNUR if, in fact, HDDs/HDFs are not present in the manufactured chemical. Finally, a SNUR could not be used to obtain information on ongoing uses.

Comment 3: EPA must establish an exposure pattern for each chemical to be tested. (CMA at pp. 2 and 4).

Response to Comment 3: EPA does not agree. As noted above, information required to make a section 4(a) unreasonable risk finding is not as extensive as that required to regulate under TSCA section 6. Furthermore, under section 26 of TSCA EPA is authorized to take action under the Act with respect to categories of chemicals. Categories of chemicals include groups that are similar in molecular structure, in physical, chemical or biological properties, in mode of entrance into the human body or into the environment or in some other way suitable for classification. The chemicals subject to this rule all have the possibility of being contaminated with HDDs/HDFs based on chemical structure, known pathways to contamination, and manufacturing conditions which are conducive to the formation of HDDs/HDFs. The HDDs/HDFs are also suitable for categorization also because, as discussed more fully in the preamble of the proposed rule and elsewhere in this preamble, HDDs/HDFs are structurally similar, certain of the HDDs/HDFs are highly toxic even at low exposure levels, there are numerous important physical/chemical similarities between the HDDs/HDFs and these physical similarities have been related to the induction of toxic effects. Thus, EPA is justified in considering these chemicals as a class for section 4 testing purposes

EPA believes there is potential for human exposure to each of the 32 chemicals when they are manufactured, processed, distributed in commerce, used or disposed of at the levels of concern stated in this rule.

Comment 4: In order to set analytic targets for impurity analysis (LOQs), EPA must collect exposure data on each individual chemical using section 8(a) of TSCA. (CMA at pp. 3 and 4; p. 4 in comments to proposed amendment adding precursors).

Response to Comment 4: EPA disagrees. As with the comments discussed above, this comment confuses the data needed to determine a level at which testing will be required with the "action" level at which regulation may be imposed under section 6 of TSCA. The preamble to the proposed rule made this distinction clear (50 FR 51800 (column 2)). EPA indicated that any action level would be derived for each individual chemical based on its contamination levels and its potential for exposure, and taking into account cost of testing and benefit to society resulting from information generated by such testing. For testing purposes the Agency chose levels that could possibly present risks of concern, using generic exposure scenarios, choosing the worst cases to ensure that EPA has adequate data to evaluate any potential risk resulting from low levels of all 7 HDDs and 8 HDFs occurring in a single chemical. Thus, the Agency can catch in its analytical net any use that could potentially cause unreasonable risk.

Comment 5: EPA has adequate information under TSCA not only to require testing under section 4, but also has all data needed to regulate the chemicals immediately under section 6, and should do so. (EDF p. 2).

Response to Comment 5: EPA disagrees. EPA lacks important data required to make the finding of unreasonable risk required by section 6, as detailed in its response to the EDF/NWF Petition at 50 FR 4428 (January 30, 1985). EPA has determined that it can find that the listed chemicals may present an unreasonable risk, as required by section 4 of TSCA, and therefore can gather the data needed to determine whether these chemicals present an unreasonable risk and whether regulation of these chemicals under section 6 of TSCA is appropriate.

Comment 6: EPA has not demonstrated that reductions below 0.1 ppb are feasible for all HDDs and 1.0 ppb for all HDFs. EPA only referenced Dow Chemical Company's studies of 2,3,7,8-TCDD reductions during the manufacture of a pesticide, 2,4,5-T; these studies only show reduction of one congener to a 10 ppb level. (CMA at pp. 22 and 23). This comment, apparently, is meant to support the position that EPA cannot make a finding of unreasonable risk for purposes of this rule.

Response to Comment 6: This comment also confuses the nature of the TSCA section 4(a) finding with the TSCA section 6(a) finding. EPA can justify testing a chemical based on the limited data indicating that Dow was able to reduce 2,3,7,8-TCDD levels in its product, thereby showing that regulation may be feasible (Ref. 12). EPA does not comment on whether such information would justify setting particular contaminant levels in products.

Comment 7: The risks from exposure to contaminants at low levels may be much lower than predicted, based on the low risk from exposure to the substance itself. Reducing the level of impurities will have negligible effects on risks from use of the commercial substance. The unreasonable risk determination must be made on the risk from the commercial substance as marketed; other determinations are useless from a risk reduction standpoint. (Dow at pp. 5 and 6).

Response to Comment 7: The effect of an impurity on risk, of course, depends on the nature of the impurity. The data on contamination of the chemical with HDDs/HDFs, gathered from this rulemaking, will be used by EPA to examine the risk from exposure to the chemical when the Agency considers regulation under section 6 of TSCA.

Comment 8: EPA must consider the conditions of use for the chemicals listed for testing, especially when the conditions involve elevated temperatures which increase the possibility of exposure to both residual HDDs/HDFs and newly formed HDDs/HDFs. Plastics workers are commonly exposed to decomposition products during equipment plugging and/or malfunctions, and firefighters and consumers are exposed to such products during fire-related exposures. (Workers' Institute for Safety and Health pp. 1 and 2).

Response to Comment 8: EPA has considered worker exposure to a chemical contaminated with low levels of HDDs/HDFs in its generic exposure scenarios. Issues of combustion products which may pose an unreasonable risk are not immediately applicable to a consideration of whether to test a chemical for HDDs/HDFs. If such contamination is found, however, this issue will be considered in the determination of unreasonable risk under section 6.

Comment 9: CMA believes that all companies required to test will be willing to do so if the program is a reasonable one. The key to CMA's reasonable program is establishment of reasonable LOQs, based on a full exposure and risk assessment for each chemical, and on demonstrated capability to analyze HDDs/HDFs in chemical matrices. The companies required to test will be willing to begin by summer (1986) and provide results within 1 year. (Transcript to April 22 meeting, pp. 5 and 6; p. 4 in comments to proposed amendment adding additional precursors.) CMA also believes the companies would be willing to provide the section 8 data required to establish exposure for each chemical to determine a reasonable LOQ based both on exposure and capability. (Transcript at pp. 7 and 8.)

Response to Comment 9: EPA's concerns with a voluntary testing program lie chiefly in the lack of enforcement powers, and the potential for lost time if CMA and EPA could not arrive at an agreement on the testing conditions. CMA implies that the Agency must collect exposure data for each chemical, and perform a risk assessment to set an LOQ for each HDD/HDF for each chemical. Then the Agency must further revise its LOQ based on what has been done in the past to analyze HDDs/HDFs in commercial chemicals. EPA rejected that approach in response to comments 2 and 3. However, to meet CMA's concerns about the low level of the LOQs as proposed, EPA has adjusted the LOQs somewhat, based on toxicity equivalencies to 2,3,7,8-TCDD. This system allows higher LOQs for higher halogenated HDDs/HDFs, which CMA has said will be the more difficult congeners to analyze. EPA has also set the LOQ not as an inflexible level, but rather as a target to be met if possible given a reasonable amount of time both for an experienced analyst and for required equipment. All of these adjustments should considerably reduce CMA's concerns.

3. *Comments on proposed findings under section 4(a)—a. Unreasonable risk.* EPA bases its unreasonable risk determination on the analysis contained in the preamble to the proposed rule (50 FR 51797–51800 and 51805–51806). The data and analysis described therein with the modifications discussed below justify a finding under TSCA section 4(a) that the chemicals subject to this rule may present an unreasonable risk, such that testing of the chemicals for HDDs/HDF is required at the LOQs described in this rule. The toxic potential of HDDs/HDFs carry considerable weight in making this determination. Two of the HDDs/HDFs which have been tested for carcinogenicity are quantitatively estimated to be potent carcinogens. Many of the remaining HDDs/HDFs, all of which are structurally similar to the two which have been tested in long term studies, have been shown to produce toxic effects in animals and exhibit biological activity in *in vitro* and *in vivo* studies at very low levels. These HDDs/HDFs may be present as impurities in certain chemicals based upon reactions which can reasonably be expected to occur under conditions expected to exist during their manufacturing processes. Therefore, people may be exposed to these chemicals and their associated impurities during production, processing, distribution in commerce, use, and disposal of these chemicals, and may thereby be at risk of potential adverse health effects associated with these impurities.

There is an indication that exposure to chemicals contaminated with 2,3,7,8-TCDD at levels as low as 0.1 ppb may pose a significant risk to workers who manufacture the chemicals. Therefore, the testing levels have been set as low as reasonably attainable, with target LOQs beginning at 0.1 ppb and adjustments for each congener based on its toxicity relative to that of 2,3,7,8-TCDD, the most toxic congener. EPA expects manufacturers to make good faith efforts to reach the target levels, but will allow reporting of higher levels if it determines, based on review of the protocol and the results of testing under those protocols, that the manufacturer has made a good faith effort to measure HDDs/HDFs as low as possible in his or her chemical. An additional reason for targeting 0.1 ppb as the LOQ for 2,3,7,8-TCDD is that the specification of this

LOQ as a target at the outset of the methods development program for a particular product can be factored into the estimated costs necessary to achieve the target LOQ; therefore, the actual cost per sample should not be significantly affected. If the requirement for a higher target LOQ were specified at the outset of preliminary method development and then lowered after initial method development were completed, an increase in cost of analysis per sample would be expected due to requirements for total reanalysis. EPA has found no reason to alter its determination that the overall costs of testing are reasonable. See Unit V. below.

Elimination or preclusion from the market due to cost of testing for individual manufacturers and individual chemicals has been considered, and EPA has allowed manufacturers to file a request for exclusion from the testing requirements if the manufacturer can also show that the chemical will not present an unreasonable risk of injury to health or the environment. Additional reasons for which an exclusion from testing may be granted are: (1) The manufacturing process is such that conditions which may lead to formation of HDDs/HDFs are not present; (2) the pre-existing test data are adequate under this rule; and (3) the chemical is produced in quantities of 100 kilograms or less per year and is used for research and development purposes. Discussion of the comments on toxicity and exposure appears below. Discussion of the comments on cost appears in Unit V.

(i) *Toxicity.* The toxicity discussion in the preamble to the proposed rule (50 FR 51797–51798) applies to EPA's toxicity finding on HDDs/HDFs. One isomer, 2,3,7,8-TCDD has been estimated by EPA's Carcinogen Assessment Group (CAG) to be the most potent of 55 suspected human carcinogens (50 FR 51798, column 1). The other HDDs/HDFs subject to this rule appear to be qualitatively similar to 2,3,7,8-TCDD in their toxic action and appear to have strong structural and chemical reactivities similar to 2,3,7,8-TCDD (50 FR 51798). As discussed below, EPA sees no reason to change these basic aspects of its toxicity finding. However, EPA has changed its determination in one respect. Rather than considering all HDDs/HDFs to be as toxic as 2,3,7,8-TCDD, EPA has used TEFs to relate the toxicity of each HDD/HDF to the toxicity of 2,3,7,8-TCDD. These TEFs have been developed by the EPA and have been favorably reviewed by the Agency's Science Advisory Board (SAB) (Ref. 35). In addition, all comments submitted in response to EPA's proposal were favorable to use of the TEFs.

Comment 10: EPA has overestimated the toxic potential of HDDs/HDFs. This is because EPA incorrectly relies on the incremental cancer risk for lifetime exposure to 2,3,7,8-TCDD developed by the Agency's CAG. This calculation is that the incremental cancer risk is 1 in a million if an individual is exposed to 0.006 picograms per kilogram of body weight per day (pg/kg/day) based on a linear low-dose model. Instead, EPA should base its determination of potency on a No Observed Effect Level (NOEL), such as that developed in an analysis by the Canadian Ministry of Environment (Environment Canada). Environment Canada recommends a maximum Allowable Daily Intake (ADI) for 2,3,7,8-TCDD of 10 pg/kg/day, which is 1,000 times higher than the EPA risk level. (CMA at pp. 14 and 15.) The Environment Canada assessment is more appropriate because it is based on the determination that 2,3,7,8-TCDD is an animal cancer promoter and not a cancer initiator. Thus, the linear no-threshold model used by EPA is not appropriate. (Dow at pp. 4.)

Response to Comment 10: EPA disagrees that it has overestimated carcinogenic potency for purposes of this rule. Rather EPA has employed a scientifically acceptable method to determine potency. This determination applied a no-threshhold, linear low-dose, multi-stage mathematical model to the results of a 2,3,7,8-TCDD feeding study by Kociba 1978 (*see* Ref. 34) that showed statistically significant incidences of tumors in the liver, lungs, hard palate, and nasal turbinates of female rats.

EPA believes that the no-threshold, linear low-dose model is appropriate for a number of reasons. First, while there is no conclusive proof that 2,3,7,8-TCDD is a cancer initiator, the biological half-life and prolonged retention time of this compound in the human body may result in "promoter effect" which is essentially irreversible (Ref. 28). Thus, although 2,3,7,8-TCDD is not a proven cancer initiator, the no-threshold, linear low-dose model is appropriate because of the plausible mechanistic model of tumorigenesis, which suggests that there is some risk of tumor formation at any level of exposure. Second, for chronic exposure of 2,3,7,8-TCDD, experimental evidence suggests a linear dose-response relationship in the low dose region for tumorigenesis and enzyme induction (Ref. 36). Finally, for 2,3,7,8-TCDD the mechanisms of carcinogenesis (the biochemical changes that ultimately result in the manifestations of cancer) are unknown. See EPA's *Health Assessment Document for Polychlorinated Dibenzo-p-Dioxins* at pages 2 through 7 (hereafter "HAD") (Ref. 34); also see Ref. 27. According to the Office of Science and Technology Policy (OSTP), (50 FR 10371, March 14, 1985), a linear low-dose model, such as the one used by EPA, is the preferred risk assessment approach if mechanisms of carcinogenesis for a chemical are not known. The EPA Guidelines for Carcinogenic Risk Assessment (51 FR 33861, September 24, 1986) agree with the OSTP policy on this point.

With respect to the promoter versus initiator issue, EPA agrees that all evidence points to the fact that 2,3,7,8-TCDD, and by implication the HDDs/HDFs in this rule, are potent cancer promotors. However, current EPA policy is contained in the Agency's Guidelines for Risk Assessment and the HAD, which concludes that 2,3,7,8-TCDD should also be treated as a cancer initiator as well as a promoter, based on a series of animal studies with 2,3,7,8-TCDD and other compounds (Ref. 34 at 11–58 and 11–59). This approach is endorsed by EPA's SAB (Ref. 35). While it is true that some experts believe that 2,3,7,8-TCDD is only a cancer promoter, and not a cancer initiator (Ref. 36), and that some agencies in other countries have acted on that belief, EPA has, at least for purposes of this testing rule, maintained the current Agency position to treat the HDDs/HDFs as complete carcinogens (capable of both promotion and initiation).

In any case, the promoter vs. initiator issue may be irrelevant for risk assessment purposes, even if 2,3,7,8-TCDD is only a promoter. The threshold model is appropriate for a promoter if the effects from the promoter are assumed to be reversible if the promoter is removed. Thus, one may estimate a level (reference dose) which would be accepted to be without risk of harmful effects in humans by applying an uncertainty factor to a threshold or NOEL level. Because retention time and biological half-life of 2,3,7,8-TCDD is so long (up to 8 years; Ref. 28), and because its "promoting action" may not be reversible, it may not be possible to estimate a Reference Dose for use in a threshold model which takes into account the manifestation of prolonged effects from multiple promoters/initiators. EPA believes that this approach more completely addresses the question of simultaneous exposure to multiple initiators in the environment at the same time, as well as exposure to accumulative doses of compounds with

g half-lives in the human body, such 2,3,7,8-TCDD.

Environment Canada based its ermination that 10 pg/kg/day is an ceptable level of exposure to 2,3,7,8-DD in humans on the fact that productive and cancer studies show observable effects in animals at a se of 0.001 µg/kg/day, and set this el as the NOEL. The NOEL is the el at which there would be no ference in risk between the pulations exposed to 2,3,7,8-TCDD d populations not exposed. A safety ctor of 100 was applied in order to ive at the 10 pg/kg/day level. Such an proach does not address the question simultaneous exposure to multiple iators in the environment at the same ne, and exposure to accumulative ses of compounds with long half-lives the human body, such as 2,3,7,8-CDD.

Thus, the difference between the 10 g/kg/day level adopted by nvironment Canada and the 0.006 pg/g/day level used by EPA reflect fferences in views of the mechanism action by which these compounds fect their toxicity, as well as tempting to estimate the effect of ultiple or additive initiators. EPA's pproach is therefore acceptable from a egulatory standpoint.

Comment 11: Evidence against EPA's nduly high estimates of toxic potency r HDDs/HDFs can be seen in results om human epidemiology studies. xposures to 2,3,7,8-TCDD among erbicide manufacturing workers were igh enough to produce readily iscernible cancer excesses if potency were as high as EPA suggests. No such xcesses have been found. Further, if EPA's potency values were correct, and f background exposures to HDDs/HDFs 30 to 40 years ago were similar to current background exposures, as suggested by Czuczwa, *et al.* (Refs. 9 and 10), a discernible upward trend in cancer mortality beginning 15 to 20 years ago would have been observed. This is not the case. In both the herbicide worker study and the predicted background levels, the number of excess cancer deaths predicted by EPA exceeds the sensitivity of measurement by a factor of 10. Therefore, the EPA potency estimate is at least ten times too large. (CMA at pp. 15 and 16.)

Response to Comment 11: EPA disagrees that the results from the epidemiology studies cited above show that EPA's estimate of the potency level for 2,3,7,8-TCDD is too high. EPA has always maintained that the Agency's estimate of toxic potency for 2,3,7,8-TCDD is in fact an upper limit; that is, the Agency does not think that the potency is likely to be greater than the given estimate and, in fact, may be less. While it may be true that the real potency may be something less than EPA's suggested upper limit, it is not clear that the scientific data base available at this time presents evidence strong enough to support some other (lower) estimate.

Further, epidemiologic studies are inherently capable of detecting only comparatively large incidences of cancer, and confounding factors such as long latency periods, bias, and poor exposure characterization often affect the adequacy of the study. The use of data by Czuczwa, *et al.* cannot be used to identify general population exposure levels, because neither study was of a statistical design from which one could infer general U.S. exposures. Czuczwa studied two lakes in Michigan, Lake Siskiwit and Lake Huron. These studies of the lake sediments show that HDDs/HDFs were deposited in lake sediments beginning around 1940, generally increasing thereafter, and that the distribution of congeners found corresponds with present-day concentrations of congeners associated with emissions from combustion of fuel and wastes. While these studies were not directly intended to address the question of general environmental levels of HDDs/HDFs, Czuczwa notes that the levels of HDDs and HDFs in the Great Lakes Basin may be higher than in other areas of the U.S. due to heavy chemical production and waste incineration.

Commenters suggested a comparison between general background levels of HDDs/HDFs and cancer mortality trends. Such a comparison is limited due to the inability to characterize general population background exposure to HDDs/HDFs. While EPA has no reason to believe that the HDD/HDF levels found by Czuczwa, *et al.*, are representative of levels in the rest of the U.S., there does appear to be a plausible basis for the hypothesis that background levels of HDDs/HDFs exist in the general population. The sources of these background levels are likely to be dispersed, and could include point sources (such as suggested by Czuczwa's Great Lakes Basin data above) that lead to general contamination of the food chain, up to and including mother's milk, for example.

If one hypothesized that general population exposures have been increasing in the last 20 to 40 years, although it is not possible to identify level or magnitude of increase, one might expect to see increases in cancer mortality. In reality, however, the incidence of most forms of cancer is generally steady or declining, with the notable exception of lung cancer (directly attributable to cigarette smoking), which is on the increase, particularly among women. Without a definitive link between general background levels of HDDs/HDFs in the environment as well as in the general population, and the current increase or decrease of specific types of cancer, the increase (or decrease) in excess cancer mortality attributable to exposure to HDDs/HDFs in the environment or the individual cannot be accurately predicted, as suggested above by CMA.

Examination of total neoplastic mortality is insensitive for this type of ecologic analysis due to a high background incidence, but examination of site-specific mortality can yield information. It is not unreasonable to look at connective tissue and soft tissue cancer mortality since a limited amount of evidence suggests this may be a target site. From this ecologic examination, an increase in connective tissue and soft tissue cancer mortality rates is seen for all races (white and nonwhite) and sexes (male and female).

The epidemiologic evidence from both Sweden and New Zealand regarding HDD exposure from contaminated herbicides and the incidence of cancer in humans have been subjected to considerable scrutiny due to poorly characterized exposure estimates and other confounding factors, but emphasizes that the epidemiological inference supporting the relationship between human exposures to phenoxy herbicides contaminated with TCDD and the occurrence of soft tissue sarcoma remains strong. EPA believes the association reported in the two Swedish soft tissue sarcoma studies are strong enough to make it unlikely that they have resulted entirely from random variations, bias, or confounding factors. A similar view has been expressed by Dr. Aaron Blair, of the National Cancer Institute (NCI), who after evaluating existing human data regarding dioxin and cancer summarized that,

> The epidemiologic evidence regarding dioxin exposure and cancer is contradictory. In fact the contradiction is striking. On one hand we have the Scandinavian studies where striking excesses of lymphoma (5-fold) and soft tissue sarcomas (3–5 fold) occur and on the other hand studies from New Zealand find no risk or only slight risk of these tumors. As it stands now the epidemiologic data are not persuasive regarding one interpretation over the other. The high relative risk seen in the Swedish studies, however, cannot be dismissed (Ref. 40).

Regarding the analysis of HDDs/HDFs in adipose tissue from persons from the St. Louis, Mo. area, the analysis of 35 samples, of which 8 showed detectable HDD/HDF levels, is too small a sample size to be representative of the U.S. population as a whole. Furthermore, the samples were not taken from a statistically-designed study. The epidemiologic studies are limited in their ability to be compared with the animal-based prediction of human cancer risk.

The issue of determining exposures in epidemiologic studies is a perennial one, confounded even more by the potential for background exposure and the existence of background levels in the general population, as discussed above. Although scientific conjecture and subsequent relative studies in the U.S. and elsewhere have not yet resolved these discrepancies, EPA maintains that this suggestive link is indicative of the unresolved concern relating 2,3,7,8-TCDD exposure to cancer in humans. Until these concerns are resolved, EPA will continue to interpret these studies as suggestive evidence of the potential carcinogenic effect of 2,3,7,8-TCDD.

Comment 12: EPA has overlooked the fact that animal species vary greatly in their toxic response to HDDs/HDFs. (CMA at p. 14.)

Response to Comment 12: EPA is aware that there is a wide species difference in toxicity for HDDs/HDFs. For 2,3,7,8-TCDD, science has been unable to determine why such variation exists, or where humans fit into the spectrum of other mammals. This issue was discussed in an EPA SAB hearing November 4, 1986, where the SAB noted that the species difference in toxic responses to different HDDs/HDFs is likely to be due to genetic, metabolism, and absorption factors. The SAB acknowledged the lack of data in these areas and encouraged EPA to sponsor research on metabolism and on carcinogenicity of untested congeners.

In the absence of data, EPA cannot say that the human is more or less sensitive than any other species. EPA's Carcinogenicity Risk Assessment Guidelines indicate that for regulatory purposes EPA will choose the most sensitive species. For HDDs/HDFs, moreover, the cause for concern is that those HDDs/HDFs which have been tested show toxic responses at very low levels. See Unit IV.A.1.a. of the proposed rule.

Comment 13: EPA assumes without verification that all HDDs/HDFs are carcinogenic, although most have never been tested for carcinogenicity. (CMA at p. 14).

Response to Comment 13: This comment misinterprets the nature of EPA's decision in this rulemaking. EPA acknowledges that few of the HDDs/HDFs have actually been tested for carcinogenicity. Only 2,3,7,8-TCDD and a mixture of 2,3,7,8-substituted Hx CDDs have been tested, but they are the most potent animal carcinogens evaluated by EPA to date. The basis of the toxicological finding in this rule is the structural activity relationships among the HDDs/HDFs. Experimental data have accumulated which clearly indicate a link between intracellular biochemical mechanism and whole animal toxicities from exposure to HDDs/HDFs. The occurrence of these biochemical phenomena appear to be closely related to the structure of the HDDs/HDFs: the more similar the structure to 2,3,7,8-TCDD the more toxic is the compound. (Refs. 3, 21, and 22). Limited *in vivo* and *in vitro* data support the structure/activity argument that 2,3,7,8-substituted HDDs/HDFs share qualitative toxicity properties with 2,3,7,8-TCDD (see 50 FR 51798). This similarity of response is noted in a wide range of toxic endpoints including limited carcinogenicity and teratogenicity results. Therefore it is prudent to consider that similar HDDs/HDFs have similar toxic potentials, including carcinogenicity (Ref. 4).

Comment 14: EPA incorrectly refers to "suggestive" epidemiological evidence linking 2,3,7,8-TCDD to the occurrence of cancer. All studies other than those of a single investigator have not found any such link and this study has been subjected to significant criticism. (CMA at p. 14).

Response to Comment 14: EPA does not mean to state that epidemiological studies are persuasive regarding any interpretation. The epidemiological evidence is contradictory. See Response to Comment 11 above. However, the high relative risk of certain Swedish studies of herbicide workers cannot be totally dismissed. Furthermore, a recent study of farmers in Kansas provides additional evidence that epidemiological evidence is suggestive of a positive link between excess cancers and exposure to a HDD-containing herbicide (Ref. 18).

Comment 15: In setting LOQs EPA should use the Toxic Equivalency Factors (TEFs) developed by the Agency. (Dow at p. 6; March 4, 1986, Hearing Transcript at pp. 12 and 13, 20 and 21; CMA at pp. 39 and 40).

Response to Comment 15: EPA requested comment on the use of its TEFs in the preamble to the proposed rule, 50 FR 51800, column 2. Since that time the concept has been reviewed favorably by the Agency's Risk Assessment Forum, the Risk Assessment Council, and the SAB (Ref. 35). Moreover, the response both from comments and from the public meetings was favorable toward using TEFs to set LOQs, although the various parties recommended different approaches to their use. CMA advocated using the TEFs along with actual exposures to each congener to develop LOQs. In contrast, the Environmental Defense Fund (EDF) recommended applying the TEFs so that the sum of all HDD/HDF congeners found in any chemical would not exceed 0.1 ppb. This would involve an analysis to determine which congeners were present, and an application of the TEFs to determine the level of quantitation for each. (March 4, 1986, Hearing Transcript at pp. 33 and 34). This would necessitate levels in the parts per trillion range, which EPA believes is not generally achievable in chemical matrices, based on experience in EPA laboratories.

Since EPA has elected to treat the chemicals as a class for purposes of this rule, EPA has rejected setting LOQs on a chemical-by-chemical basis, as noted above in response to comment 4. With respect to EDF's scheme, EPA believes that these LOQs would be too low to be reasonably and accurately measured.

EPA has decided to use 0.1 ppb as a target level for 2,3,7,8-TCDD, because the Agency's generic assessment of risk shows a potential worst-case risk from dermal exposure to workers from that congener present at that level, and has set target LOQs for all other congeners at some level above 0.1 ppb because those congeners are, according to the TEF scheme, likely to be less toxic than 2,3,7,8-TCDD.

With regard to the brominated species, EPA had a different problem since the TEFs have been set only for chlorinated HDDs/HDFs. Thus, EPA had the choice of setting the LOQs for the brominated HDDs/HDFs at the same level as their chlorinated counterparts, based on the assumption that the brominated counterpart is equally toxic, or of leaving the LOQ for brominated HDDs/HDFs at the proposed level of 0.1 ppb. Very little data have been collected on brominated HDDs/HDFs, but that which have been collected suggest that brominated HDDs/HDFs are generally as toxic as their chlorinated analogues (Ref. 25).

For purposes of this rule, EPA has assumed equal toxicity, and has adjusted the LOQs for brominated HDDs/HDFs to match those of their chlorinated analogues.

The new LOQs are as follows: 0.1 ppb for T_4HDDs; 0.2 ppb for P_5HDDs, 2.5 ppb for Hx_6HDDs; 100 ppb for Hp_7HDDs; 1.0

ppb for T_4HDFs; 1.0 ppb for P_5HDFs; 10 ppb for Hx_6HDFs; 100 ppb for Hp_7HDFs.

Comment 16: EPA should eliminate the heptahalogenated congeners from the testing requirement because toxicity for these congeners is orders of magnitude less than that of 2,3,7,8-TCDD. (CMA at p. 42).

Response to Comment 16: EPA agrees that its TEF scheme indicates that the heptahalogenated congeners are considerably less toxic than 2,3,7,8-TCDD, but does not agree that they should be dropped from the testing requirement. In chemicals which have been tested, such as pentachlorophenol, the heptachlorinated dioxins are present in such large quantities that they could produce a toxic effect, even though their individual toxicity is many times lower than that of 2,3,7,8-TCDD (Refs. 4 and 8). In addition, the higher halogenated congeners have a tendency to dehalogenate in the presence of light to lower halogenated, and more toxic, congeners. (April 22, 1986, Hearing Transcript at pp. 46 and 47; comments submitted by Cambridge Isotope Laboratories (CIL)). There is also some evidence that higher halogenated HDDs/HDFs may have longer half lives in the human body, thereby enhancing their toxic potential (Ref. 28). For these reasons EPA has not removed the heptahalogenated congeners from the testing requirement, but has adjusted the LOQs based on the TEFs.

Comment 17: EPA should not have excluded iodinated and fluorinated species from this rule. Studies suggest that fluorinated dioxins are more biologically active than chlorinated or brominated ones and there is the possibility that fluorinated compounds could replace chlorinated or brominated compounds. (March 4, 1986, Hearing Transcript at p. 9; EDF at p. 5; p. 2 in comments to proposed amendment adding additional precursors).

Response to Comment 17: EPA has decided not to focus on the fluorinated and iodinated compounds in this rule. Straight substitution of fluorine or iodine for chlorine or bromine produces compounds with considerably different physicochemical and biological properties, thus indicating that fluorine and iodinated compounds would not be good substitutes for chlorinated or brominated compounds as commercial products. However, it is possible that fluorinated and iodinated compounds (which may theoretically be predisposed to HDD/HDF contamination) may be used to formulate commercial chemical products on an increasingly larger scale in the future. At the present time, however, the use of these compounds in the manufacture of commercial chemical products is small in comparison to the number of products using chlorinated or brominated chemicals.

Development of the analytical methodology, including appropriate standards, necessary to ensure accurate analysis with appropriate QA/QC procedures for the iodinated and fluorinated compounds does not appear to be cost effective at this time. There is no indication that any commercial laboratory is attempting to make such standards, and the cost of developing standards was one of the major costs of this final rule.

EPA may receive information, either as a result of the reporting requirements in this rule, or from information reported to the Agency in response to requirements promulgated under TSCA or other statutes, on the production, use, or disposal of these iodinated or fluorinated compounds. In the event this information indicates that these chemicals are being used on an increasingly frequent basis to replace chlorine and bromine in the manufacture of chemicals to which persons may be exposed, EPA will investigate, as it has for the chlorinated and brominated chemical compounds in this final rule, the potential for contamination with HDDs/HDFs, the likelihood of subsequent human exposure and the potential for unreasonable risk.

(ii) *Exposure.* EPA's proposed rule estimated exposure to the HDDs/HDFs subject to this rule by analyzing the risks that could theoretically occur if the chemicals subject to testing were contaminated with 2,3,7,8-TCDD, and by implication the other HDDs/HDFs, in the 0.1 ppb to 1.0 ppm ranges. The Agency applied these ranges to representative exposure scenarios consisting of dermal exposure to a household cleaner and to chemicals in the workplace. Theoretical risks resulting from the 0.1 ppb and 1.0 ppm contamination levels in the representative exposure scenarios were calculated using Lifetime Average Daily Dose (LADD) values in the multistage linear low-dose model discussed above. (See 50 FR 51786–51789). The risks ranged from a theoretical 1 in 1 occurrence for occupational dermal exposure at a contaminant level of 1 ppm to an individual risk level of approximately 4 in 10 million for consumer exposure to household cleaners contaminated at 0.1 ppb.

EPA acknowledges that much of the exposure analysis in the proposal indicated a higher risk than may be expected; however, after analyzing the comments on its exposure modeling, the Agency has concluded that, for purposes of this rule, the 0.1 ppb LOQ is an appropriate target level for testing 2,3,7,8-TCDD. This is based on modifications to the existing occupational exposure scenario, which indicates there could be potential risk to chemical workers from 2,3,7,8-TCDD exposure at 0.1 ppb. The same target LOQ has been set for 2,3,7,8-TBDD. As noted above, the target LOQs for the other HDDs/HDFs have been adjusted upward using the TEFs. Analysis for any HDDs/HDFs in chemical matrices down to 0.1 ppb will be very difficult, but especially difficult for higher halogenated HDDs/HDFs. However, the toxicity of the HDDs/HDFs in this case may be expected to decrease with the degree of halogenation, so that use of the TEFs adjusts the LOQs upward for the higher halogenated congeners. EPA has also set the LOQs as a target, since the levels set may not be achievable in some chemical matrices. A review of the cost of analysis on a per-sample basis at these target levels indicated that the differences in costs associated with analysis at higher levels are not appreciably significant if the target LOQ is specified at the outset in analytical method development. If the target LOQ were established at a higher level before allocation of resources for method development, then lowered to a more conservative target level, an increase in cost per analysis would be expected because of reanalysis at the lower level. The exposure scenarios show that the risks posed by exposure to workers at the 1 ppm range may be substantial. Therefore, EPA has decided that the modified occupational dermal exposure scenario provides an adequate basis for choosing 0.1 ppb as the appropriate target testing level for the tetra HDD/HDF congeners, which are those of greatest concern to the Agency. Choosing the 0.1 ppb level as the lowest testing level will allow EPA to evaluate any of the potential risks resulting from low levels of all the HDDs/HDFs once the testing data are submitted, and will allow the Agency to catch in its analytical net any use that could potentially cause unreasonable risk, including possible new uses.

In addition, it is better to analyze these compounds at low levels when they are first created, rather than wait until they have entered environmental pathways, such as food chains and water supplies, and may have caused widespread contamination. In addition, because these compounds are difficult to monitor at trace levels in the environment using standard techniques, they are best analyzed when they are first created in the manufacturing

process for later prediction of environmental contamination.

EPA's responses to comments on its exposure analysis are discussed below.

Comment 18: EPA's consumer exposure scenario based on a household cleaner is not representative of the uses of the chemicals subject to this rule, since none of those chemicals are used in such products and many are used almost exclusively in applications in which they are bound into polymeric matrices and thus are unavailable for human exposure. In fact, the household cleaner scenario is based on use of phenolic compounds in pesticides, which are not subject to TSCA jurisdiction. (CMA at pp. 18 and 19.)

Response to Comment 18: EPA concludes that the household cleaner scenario is relevant to this rulemaking. While the specific scenario used by EPA on household cleaners is based on a pesticide use not subject to regulation under TSCA, EPA has no indication that the chemicals subject to this rule may not be in products intended for similar uses that may be subject to TSCA. For example, no comments indicated that particular chemicals are not or could not be used for some kind of sprayed application or might not have some potential high exposure pattern. Indeed, there is some evidence that the use of certain chemicals may possibly result in high exposure patterns, most notably compounds used as additive or blended fire retardants, or as dye carriers for textile dyes. An additive fire retardant is topically applied to the desired materials (e.g., fabric, wood, synthetics), rather than incorporated into the product matrix by physical bonding or chemical reactivity (Ref. 13).

Since EPA has some indication that chemicals related to chemicals subject to this rule may be used in high exposure situations, manufacturers of the chemicals subject to this rule have an affirmative duty to inform the Agency that the chemicals, in fact, are not used in high exposure situations, and could not be used in high exposure situations. After all, manufacturers should have such information in their possession and in many cases may represent the only way in which EPA may obtain it. Instead, CMA, the representative of the industry, only states that none of the chemicals to be tested is "currently" used in household cleaner applications and that "many" of the chemicals are used "almost exclusively" in bound matrices. (CMA at 19). EPA assumes this statement does not refute the Agency's determination that the chemicals could possibly be used in high exposure situations or that some are currently being used other than in bound matrices. Indeed, while a particular manufacturer may feel confident that its current uses are in totally bound matrices, the same manufacturer may develop a new high exposure use in the future or another manufacturer may be currently producing the same chemical for a high exposure use.

The household cleaner analysis, therefore, which shows individual risks at 4 in 10 million for the 0.1 ppb level and individual risks of 4 in 1 thousand at the 1.0 ppm level, merely indicates that EPA, for testing purposes, should be concerned with some intermediate level, if no other risk scenario were to apply. Of course as noted above and more fully discussed below, the dermal occupational scenario gives EPA reason to believe that the 0.1 ppb level may be of concern for some HDDs/HDFs.

Comment 19: Even if EPA's calculations regarding risk of the household cleaner scenario are relevant to this rule, the Agency's calculations are unrealistic. A realistic scenario demonstrates that this use would not pose an unreasonable risk even if 2,3,7,8-TCDD were present at 1 ppm. If a disinfectant with active ingredients present at 0.1 percent levels were contaminated with 1 ppm HDDs/HDFs, once weekly usage, even assuming 100 percent absorption, over 55 years would yield a LADD of 4.8×10^{-10} mg/kg/day (4.8×10^{-7} µg/kg/day). This is two orders of magnitude less than EPA's LADD of 2.7×10^{-5} µg/kg/day. (CMA at pp. 18 and 19).

Response to Comment 19: EPA rejects this comment. The Agency's calculations at the 1 ppm contamination level are reasonable. The difference between the two calculations results from CMA's assuming active ingredients present at 0.1 percent and EPA's assumption of a 4.5 percent active ingredient concentration. EPA's assumption comes from a common household cleaner label. CMA gives no reason for assuming a 0.1 percent level, or why that level is more appropriate than EPA'S level. The remainder of the difference is accounted for by EPA's assuming a 70-year lifetime exposure and CMA's assuming 55 years. CMA gives no reason why EPA's assumption is incorrect, or why EPA should deviate from its usual assumption. In any event, the difference between these two assumptions is negligible for analytical purposes.

EPA's individual risk analysis at 1 ppm concentration in household cleaners of 4 in 1,000, therefore, is a reasonable calculation and gives EPA cause for concern.

Comment 20: A more relevant worst-case consumer exposure scenario would be the leaching of chemicals from plastic handles containing flame retardants. This shows a negligible consumer exposure. This exposure scenario, even with chemicals contaminated with HDDs/HDFs at 1 ppm, shows a worst-case LADD at 1.3×10^{-9} mg/kg/day (1.3×10^{-6} µg/kg/day). (CMA p. 20).

Response to Comment 20: EPA disagrees that the plastic handle scenario is the worst-case consumer exposure scenario that should be used for this rule. As noted above, EPA believes that the appropriate analysis to use is the household cleaner scenario. Furthermore, the LADD calculated by CMA would still present a risk of concern for testing purposes under EPA's linear low-dose risk assessment model, because CMA's calculated worst-case LADD of 1.3×10^{-9} mg/kg/day (1.3×10^{-6} µg/kg/day) would still yield oncogenic risk estimates higher than 1×10^{-6}. This level can be used as a trigger for testing purposes, given EPA's other concerns with respect to the chemicals subject to this rule.

Comment 21: EPA's worker exposure scenarios are unrealistic. The Agency assumes that both hands are immersed in the chemical daily, despite the fact that in some cases, such as 2,4-dichlorophenol, a single such incident would cause severe thermal and chemical burns. Similar burns would be expected for most of the chemicals to be tested as they are high-melting solids. In fact, using medical records from certain chemical companies showing average worker dermal exposure of less than 2 cm^2 skin surface per year, and assuming the material contains 1 ppm 2,3,7,8-TCDD, the LADD would be only 8.7×10^{-11} mg/kg/day (8.7×10^{-8} µg/kg/day). This contrasts with EPA's LADD of 0.1 ppb of 2.11×10^{-6} µg/kg/day (or 2.11×10^{-3} µg/kg/day at 1 ppm.) (CMA at pp. 20 and 21).

Response to Comment 21: EPA's exposure scenario is not a statement by the Agency that workers would, in fact, immerse their hands in vats of chemical liquids; rather, the scenario is a quantitative surrogate for the types of exposures that may occur in a chemical plant, usually as a result of accidental spills, resultant cleanup efforts involving the lack of protective clothing (e.g., gloves, goggles, etc.), and instances of worker negligence in handling small amounts of potentially hazardous chemical substances. Thus, EPA's intent was not to suggest that worker exposure results from total immersion of the hands in chemical liquids, but rather to provide a worst-case estimate based on the total unprotected area of the hands which could be exposed resulting from

these types of spills, cleanup efforts, or improper handling practices.

In response to comments regarding the reasonableness of EPA's estimate of worker exposure, EPA re-evaluated its occupational exposure estimates. EPA contacted representatives of OSHA, NIOSH, the American Industrial Hygienists and the American Council of Government Industrial Hygienists to solicit data on the reasonableness of EPA's exposure assumptions (Ref. 42). Although EPA's contacts were unable to provide estimates for the entire chemical synthesis industry (because of substantial differences among the processes, worker activities and industrial hygiene practices), they did agree that the assumption that a skin area equal to both hands, exposed to a chemical each day, is too high. Based on their information EPA believes a more reasonable estimate ranges from the area of 1 hand to the area of one-half of 1 hand exposed to the chemical substance during each time, or event, when the worker is exposed, or an estimate of 10 percent of the skin area equivalent to 2 hands exposed each day.

To estimate the number of times a worker is exposed to a chemical each year, EPA used as a surrogate an estimate of 77 as the average number of drumming, bagging and transfer operations per year. Then EPA calculated the LADD assuming that both an area equal to one-half of 1 hand and an area equal to 1 hand, was exposed to the chemical substance each time. The LADD for one half of 1 hand exposed, if the chemical is contaminated at 0.1 ppb is 2×10^{-7} µg/kg/day. The LADD for 1 hand exposed, if the chemical is contaminated at 0.1 ppb, is 4×10^{-7}; both LADD's result in a risk of 10^{-6}. If the assumption is made that only 10 percent of the skin area of a worker's 2 hands will be exposed to the chemical substance each work day, the LADD is 2×10^{-7}, again resulting in a risk of 10^{-6} (Ref 42).

Minor differences in several other assumptions account for the remaining difference in the LADDs, but these differences are insignificant. For example, EPA assumed the liquid film thickness on exposed skin surfaces at 1.8×10^{-3} cm; the density of the liquid at 1.38 gm/cm^3, and the number of years of exposure at 70 years. CMA assumed liquid film thickness at 1.5×10^{-3} cm, a liquid density of 1.3 gm/cm^3 and 55 years for lifetime exposure.

EPA believes that CMA's suggestion of an average dermal exposure of less than 2 cm^2 skin surface per year is unrealistic based on normal chemical manufacturing practices, including accidental spills and resulting cleanup efforts involving lack of protective clothing, and even isolated instances of worker negligence in handling such chemical substances. Unless the event is serious or widespread enough to cause a slowdown or halt of the production process, the event usually goes unreported. The estimate of skin area exposed during chemical manufacture by the personnel contacted by EPA are orders of magnitude larger than CMA's 2 cm^2 per year (Ref. 42).

Comment 22: Hypothetical worker inhalation exposures show extremely low LADDs and would not justify the LOQs in this rule. (CMA at p. 21).

Response to Comment 22: Because of the very low vapor pressure of 2,3,7,8-TCDD in its pure form (1.7×10^{-6} mm/Hg), inhalation toxicity scenarios were included in a support document (Ref. 43) but were not used to calculate exposures for purposes of this rule. These calculations can provide LADDs which may be useful in assessing an overall estimate of risk when considered with risk estimates based on other routes of exposure but, taken alone, do not allow a meaningful evaluation of potential risk. While EPA is unable to state whether risk from inhalation exposure, alone, is significant, such risk adds to the Agency's concern when considered with risk from possible dermal exposure.

(iii) *Exclusions and waivers.* EPA will exclude chemicals from testing based upon submission of prior test data which satisfy TSCA section 4(a)(1)(a)(i) requirements, or submission of detailed process and reaction condition data which show that conditions known to be conducive to HDD/HDF formation are not present. EPA will waive testing requirements for any chemical produced in quantities of 100 kg/year or less for purposes of research and development. When production of that chemical exceeds 100 kg/year, the waiver expires, and the producer then becomes subject to the testing requirements in this rule. EPA will also waive testing requirements for those developmental chemicals that, due to the costs of testing, either will be taken off the market or will not reach the market. While EPA believes that a potentially highly toxic chemical should not be marketed if it cannot bear the costs of testing, the Agency will consider a waiver to testing in appropriate circumstances.

If a manufacturer has a developmental chemical that, due to the costs of testing, either will be taken off the market or will not reach the market, it may apply for a waiver by submitting information to EPA that shows such adverse market effects. EPA will evaluate that information to determine whether the manufacturer's allegations of market effects will, in fact, occur. If EPA agrees with the manufacturer, the Agency will then weigh the potential risks of the chemical against the costs of testing to determine whether testing is warranted under this rule even at the developmental stage. EPA will grant the waiver, with appropriate conditions, if the risks do not outweigh the costs of testing for that particular chemical. These criteria are similar to those EPA employs in evaluating whether chemical substances should be restricted under section 5(e) of TSCA.

EPA expects this waiver to be applicable only to chemicals manufactured in amounts of no more than 2,000 to 5,000 total pounds annually. Preliminary analysis of data submitted for this rule shows that this waiver will apply to only one chemical produced by Arco Specialty Products Division, which was recently sold to Horsehead Industries.

b. *Insufficient data.* In the preamble to the proposed rule EPA stated that, with the exception of some data on 2,3,7,8-TCDD and even less data on several related congeners, the Agency has little or no data on concentrations of HDDs/HDFs in commercial chemicals upon which to base a determination of unreasonable risk (50 FR 51800). EPA received comments relative to this issue on two chemicals, and discusses those comments below. As a result of the data submitted, the Agency has excluded 1 grade of decabromodiphenyl oxide produced by DOW, for which a 2-year bioassay and an analysis for HDDs/HDFs in the test article was done. For Tetrabromobisphenol-A, the other chemical on which comments were received with respect to insufficient data, the Agency sees no reason to change its determination that existing data is insufficient and thus testing is necessary to obtain that data.

Comment 23: Existing bioassay data plus chemical analysis for HDDs/HDFs for decabromodiphenyl oxide provide all data needed to show absence of unreasonable risk. Acute, 28-day feeding, mutagenicity and 2-year feeding studies found no significant adverse toxicologic effects for decabromodiphenyl oxide. An analysis of the test article used in these studies for the presence of HDDs/HDFs revealed none present at 1.0 ppb, the lowest level achievable in the analysis. (CMA p. 24, Dow pp. 5–6).

Response to Comment 23: EPA has examined the data submitted on decabromodiphenyl oxide in which toxicology and carcinogenesis studies

were performed by NTP, along with a chemical analysis for the presence of HDDs/HDFs. The toxicology and carcinogenesis studies were performed on both rats and mice, at doses of 0, 25,000 and 50,000 ppm in the diet. Results included increased incidences of neoplastic nodules of the liver in low dose males, and in high dose groups of each sex, equivocal evidence of carcinogenicity for male mice as shown by increased incidences of hepatocellular adenomas or carcinomas (combined) in the low dose group and of thyroid gland follicular cell adenomas or carcinomas (combined) in both dosed groups, and no evidence of carcinogenicity for female mice. An accompanying analysis by NTP with appropriate QA/QC and using GC/MS, showed no HDDs/HDFs in the 2 samples analyzed at the level of 1 ppb. While EPA does not necessarily concur with the fact that the tests show no unreasonable risk, the Agency does agree that testing under this rule would not be warranted, in view of the extensive bioassay data combined with existing test data with adequate QA/QC. Therefore, EPA will exempt the grade of decabromodiphenyl oxide produced by Dow for the research NTP project, provided Dow can supply evidence showing which grade was produced for the NTP project. If Dow produces other grades by different processes, or produces by the same process a grade in which higher temperatures or more alkaline conditions occur, that grade will have to be tested under this rule.

Comment 24: The Interagency Testing Committee (ITC) has determined that Tetrabromobisphenol-A (TBBPA) should not be recommended for health effects testing, and EPA has accepted that recommendation. Thus, the compound, containing whatever HDD/HDF impurities may be present, has already been found to demonstrate absence of unreasonable risk. (CMA pp. 24 and 25 and Dow pp. 5 and 6).

Response to Comment 24: EPA did not find that TBBPA did not present an unreasonable risk to human health in accepting the ITC's recommendation to not require health effects testing. A determination that a chemical does not present an unreasonable risk can only be made after extensive testing. The issue of contamination by HDDS/HDFs was not examined at the time TBBPA was evaluated as a candidate for testing by the ITC, and the short-term tests which showed low mammalian toxicity would not be capable of identifying the latent toxic effects characteristic of 2,3,7,8-TCDD. However, in September 1986, a paper was presented which showed HDD contamination of TBBPA (Ref. 30). Therefore, there is a basis for requiring testing of TBBPA in this final rule, and this finding is not inconsistent with EPA's earlier decision not to include health effects testing of TBBPA.

c. *Necessity for testing.* EPA has determined that testing is necessary to generate data on which to base toxicity and exposure, because such data are fundamental to the assessment of risk, and because the analytical data generated by required testing in this final rule is currently not available in any accessible or usable form for purposes of assessing these potential risks. No comments other than those already addressed in comments 23 and 24 above were received on the necessity for testing.

EPA has decided, however, that it is not necessary to test under TSCA two chemicals originally proposed for testing. These chemicals are 2,4-Dichlorophenoxyacetic acid (2,4-D) and 2,4-Dichlorophenoxybutyric acid (2,4-DB). Both are registered pesticides as well as isolated intermediates used to produce pesticides. Used as pesticides, they are subject to testing under FIFRA. Used as pesticide intermediates, they are subject to testing under TSCA. At the time this rule was proposed, plans had not been completed to require testing of these pesticides under FIFRA, so they were listed in the proposed rule. EPA plans to require under FIFRA equivalent testing of pesticides for contamination by HDDs/HDFs. EPA believes that testing these two chemicals under TSCA would be duplicative and unnecessary, particularly since EPA does not expect them to be used for non-pesticide purposes. Accordingly, they will not be subject to the testing provisions of this final rule under TSCA, but instead are subject to the FIFRA Data Call-In program. They will be subject to the same testing provisions as chemicals listed for testing in this final rule, including target LOQs, the same methods, QA/QC procedures, and under the same deadlines as the chemicals listed for testing in this final rule.

EPA has also examined another chemical that has both pesticide uses, as well as non-pesticide uses subject to TSCA jurisdiction, and has decided, similarly, that testing is not necessary under this rule because that chemical is being tested under Data Call-In provisions of FIFRA. This chemical, pentachlorophenol, was not originally proposed for testing, but EPA subsequently learned that it has non-pesticide uses. Nevertheless, EPA has decided that testing under TSCA is not necessary for pentachlorophenol because such testing would be duplicative of the testing under FIFRA. However, because pentachlorophenol has uses other than as a pesticide, data collected through the OPP Data Call-In will be available for OTS review and evaluation.

B. Requirements Under Section 4(b)

Section 4(b) of TSCA, discussed in detail in the preamble to the proposed rule (50 FR 51797, cols. 1 and 2), requires EPA to deal with a number of issues before promulgating a test rule. Section 4(b)(1) sets forth three additional issues to be included in a test rule. First, EPA must identify the chemical substances for which testing is required under the rule. Second, EPA is to include "standards for the development of test data." Third, section 4(b) requires EPA to specify the period within which persons required to conduct tests shall submit data to EPA. In determining the standards for development of test data and the period for submission of data, EPA's considerations shall include the relative costs of the various test protocols and methodologies that may be required and the reasonably foreseeable availability of facilities and personnel needed to perform the testing required. Section 4(b)(3)(B) sets forth the criteria for determining who should test.

The preamble to the proposed rule discusses the section 4(b) considerations (50 FR 51800). Below, EPA discusses the comments received on these issues and the changes the Agency has made to its final regulation.

1. *Identification of substances to be tested.* EPA chose the chemicals for testing based on two broad criteria. Some chemicals have actually been tested in the past and found to contain 2,3,7,8-substituted HDDs/HDFs. The others are chemicals which EPA has good reason to believe are contaminated based on structural similarities with the chemicals actually tested, and the use of manufacturing process conditions believed to aid the formation of dioxins and dibenzofurans. Thus, these listed chemicals contain carbon and utilize chlorinated and/or brominated compounds in their manufacture and are manufactured under circumstances that include high temperature or pressure and the presence of alkaline conditions.

Contamination of the listed chemicals is expected to occur during manufacture. Thus, the focus of the testing is on detecting contamination at the beginning of the manufacturing chain to allow EPA to draw conclusions about the degree of contamination during further processing

of the chemical. Comments on chemical identification are discussed below.

Comment 25: The process and reaction conditions under which brominated phenolics are produced make it unlikely that dioxins or furans of concern will be formed. These chemicals should be removed from the list of chemicals to be tested. (Great Lakes p. 17; p. 4 in comments to proposed amendment adding additional precursors; Ameribrom p. 2.)

Response to Comment 25: Confidential data detailing the manufacturing process and reaction conditions were submitted by these commenters. These commenters provided detailed data to substantiate their claim that the processes under which certain chemicals are produced are different from those assumed by EPA, and that reaction conditions are such that HDDs/HDFs would not be expected to form. EPA has asked several clarifying questions about the process and reaction condition data submitted. The response to these questions will form the basis for a decision by EPA to exclude or waive a company from testing certain specific chemicals based on a process different from that expected by EPA and reaction conditions not expected to form HDDs/HDFs.

Even if the exclusions or waivers are granted, EPA will not remove the chemicals from the list, however, since another manufacturer may use the process specified by EPA to produce these chemicals, thus making production of HDDs/HDFs likely.

Comment 26: EPA's list of chemicals to be tested is too narrow, and must be broadened to include all chemicals likely to be contaminated with HDDs/HDFs, as were included on the list of 238 chemicals from which EPA chose those to be tested under this rule. (EDF at p. 5; p. 2 of comments to proposed amendment adding additional precursors.)

Response to Comment 26: EPA disagrees. The list of 238 chemicals which was widely circulated in July 1985, to get early comment from all segments of the community most involved with HDD/HDF analysis, was compiled from every available reference in which chemicals theorized to contain HDDs/HDFs were listed. Its purpose was as a starting point for additional analysis. Its circulation was to get input on chemicals or classes of chemicals which should or shouldn't be included, and the reasons therefor. The breakdown of this list is detailed in Reference 43 to this rule. EPA first looked for chemicals which in the past have been tested and found to contain HDDs/HDFs. Chemicals structurally similar to these chemicals, with a theoretical chemical pathway to HDD/HDF formation, and manufactured under conditions likely to produce HDDs/HDFs have been listed for testing. For the other chemicals, there is not a strong theoretical basis at present to conclude that the chemicals are contaminated with significant levels of HDDs/HDFs, due to lack of any documented pathway for HDD/HDF formation and lack of favorable process conditions. In several cases chemicals were not listed because contamination would occur from a contaminated feedstock chemical, which was already listed. The rationale is that a chemical testing contaminated will undergo further investigation, including investigation of contamination of all chemicals produced from the known contaminated chemical. Thus testing at this time is not indicated for the downstream chemicals. Finally, those chemicals with uses only as pesticides were separated into a separate list.

The result of this selection process is the list of 32 chemicals, 12 manufactured and 20 not currently manufactured, which are required to be tested under this rule.

Comment 27: EPA has omitted the halogenated anilines and benzenes and most diethyl ethers from consideration for testing, although the publication "Dioxins" (Ref. 15) and the support document (Ref. 43) cite these chemicals as highly likely to be contaminated. Further, it is well known that heating halogenated benzenes will yield PHDDs. (EDF p. 4.)

Response to Comment 27: EPA disagrees that halogenated anilines and diethyl ethers should be added as a class of compounds. Although the halogenated anilines were cited as highly likely to be contaminated (Ref. 43), the formation of HDDs/HDFs during their manufacture is dependent on specific reaction criteria of heat, pressure, alkalinity and duration of reaction employed in manufacturing the chemical. In most cases such conditions are not believed to be present in their manufacture. However, several halogenated anilines are listed as precursor chemicals, since they are believed to be conducive to the formation of HDDs/HDFs, and the application of heat during the synthesis of other chemicals could produce HDDs/HDFs in those other chemicals. Conversely, pentachlorobenzene, which may be predisposed to HDD/HDF contamination during synthesis, would require dechlorination in an aerobic environment at high temperatures to produce chlorinated dioxins or furans. This combination of reaction conditions is unlikely under current manufacturing processes.

Diethyl ethers are not discussed in either Reference 43 or in the publication "Dioxins" (Ref. 15).

As a result of EDF's comments and additional information received after publication of the proposed rule, EPA issued an amendment to the proposed rule (51 FR 37612; October 23, 1986), proposing to add 18 chlorinated and brominated benzenes to the original list of 12 precursor chemicals. This rule adds 17 of those chemicals to the category of precursor chemicals and requires reporting under section 8(a) of TSCA on chemicals made from those precursors. If process and reaction condition data submitted show that HDDs/HDFs are likely to be formed, additional chemicals may be listed for testing.

Comment 28: EPA should require testing of precursor chemicals. (EDF p. 5.)

Response to Comment 28: EPA disagrees. The precursor chemicals are listed separately because they do not meet EPA's criteria for testing, namely, the reaction conditions needed to form HDDs/HDFs are not present. All published research shows that heat, pressure and alkalinity, or some combination of these conditions, are needed for the formation of HDDs/HDFs.

These chemicals are listed as precursors because the application of the listed conditions during further chemical processing may occur, and may produce HDDs/HDFs in the final chemical substance produced. Reporting of process data and reaction conditions will help EPA determine whether any of the chemicals manufactured from these precursors should be proposed for testing.

Comment 29: EPA does not specify what grade of substance must be tested. (Dow p. 19.)

Response to Comment 29: EPA requires that manufacturers test chemicals which are listed in this final rule in all grades normally marketed in active commerce only if manufacture occurs by different processes. If manufacturing occurs by the same process under variable conditions, the test substance may be a single grade: the grade subject to the most intense heat and alkalinity for the longest duration. If these two factors do not differ for the various grades, the test substance should be the grade with the highest volume of sales. In the test protocol, the manufacturer must tell the Agency how many grades of the chemical are produced and describe the

reasons for choosing the grade to be tested.

2. *Standards for the development of test data.* This term is defined under section 3(12) of TSCA and refers to the prescription of the information for which test data are to be developed and any analysis to be performed on such data. It also includes the manner in which the data are to be developed, the specification of any test protocol or methodology, and any other requirements needed to provide assurance of the reliability and adequacy of the data. These standards should be differentiated from analytical standards, which are reference chemical materials used to calibrate and quantitate specific substances.

a. *General analytical method consideration.* The analytical procedures specified in this final rule for the quantitative measurement of HDDs/HDFs in commercial products include: (1) The quantitative extraction or partitioning of the analytes from the commercial product; (2) separation of the HDDs/HDFs from interferences present in the extract; and (3) separation, identification and quantitation of HDD/HDF congeners, using high-resolution gas chromatography (HRGC) and high-resolution mass spectrometry (HRMS) or low-resolution mass spectrometry (LRMS), if it can be shown to be as effective as HRMS for a particular matrix.

The most significant difference in the analysis of HDDs/HDFs in commercial products in comparison with environmental and biological samples will be the extraction and cleanup procedures. The physical and chemical properties of environmental and biological matrices are typically different enough from the properties of the analytes to allow relative ease of separation. In contrast, the commercial products, in most cases, may be structurally similar to the analytes, complicating the separation and necessitating the complete removal of the matrix to avoid interferences in the final determination (Ref. 24). The analyst is therefore confronted with a choice of two basic options in achieving final analysis: (1) The analyst can develop sample preparation procedures that effectively separate the commercial product matrix from the HDDs/HDFs that allow for LRMS analysis at the LOQs designated in this final rule; or (2) the analyst can elect to prepare samples in which some potential interference remains, but rely on the resolving capabilities of HRMS to distinguish the difference from HDDs and HDFs and potential interference at the LOQ. The option for use of LRMS is viable only to the extent that the analyst can demonstrate that the LOQ specified in this final rule can be achieved using this method.

b. *Detection method.* In the proposed rule, EPA chose HRGC/HRMS as the analytical method of detection (see 50 FR 51801, unit IV.B.2.b.).

Comment 30: EPA has failed to consider that the differences in the nature of halogenated compounds would present problems in loss of sample during the detailed extraction and cleanup procedures necessary to prepare samples for analysis by HRGC/MS. Dow states that extensive experience exists with samples of the chlorinated species, while very little work has been done on the brominated species. Dow predicts that problems with chemical reactivity and heat and light stability will present major problems in preparing these brominated species for analysis. (Dow p. 14; CMA p. 45).

Response to Comment 30: EPA agrees with these observations, and, based partly on these comments, has extended the required reporting deadline for submission of study plans for the analysis of totally brominated compounds for an additional year after the effective date of this final rule. The deadline for reporting the results of analyses of these compounds is within 6 months after EPA review of these study plans.

EPA has extended these deadlines because of the lack of experience in analyzing brominated compounds for HDDs/HDFs at these low levels. An extension of a year will provide time to modify and perfect for brominated compounds the methods used to analyze chlorinated compounds. The additional time also allows more freedom in scheduling available laboratory capacity to perform these analyses.

Comment 31: Dow noted that the HRMS recommended for testing would not scan the atomic mass unit range but would use single ion monitoring. Because of the difference in atomic mass between chlorine and bromine, Dow asserts, many of the instruments used for molecular ions up to octachlorodioxins and octachlorofurans are not suitable for any brominated materials above the tribrominated compounds (e.g., tetra thru hepta). This will result in the necessity of procuring a separate instrument for detection of the chlorinated and brominated congeners. Dow notes that their instrument, a quadrupole mass spectrometer with molecular ion capability up to 600 atomic mass units, would allow analysis up to and including the pentabrominated congeners, but would not allow similar analysis of hexa- or heptabrominated congeners. (Dow p. 14).

Response to Comment 31: EPA agrees that Dow may need a separate instrument to analyze for higher brominated HDDs/HDFs, but notes that newer quadrupole instruments capable of extending detection at the higher atomic mass units required for the brominated HDDs/HDFs are available (Ref. 36). EPA recognizes that the analyses of these compounds can possibly best be achieved using magnetic sector focusing instruments. This final rule does not define the resolution mode (increment of mass/mass of interest) necessary to complete the analysis. Since HRMS magnetic sector instruments may be operated in either high or low resolution modes, the analyst has the opportunity to define instrument parameters to meet the requirements for a specific analysis.

This does not mean that manufacturers required to analyze brominated dioxins and furans must make large additional investments in new intrumentation solely for the purpose of completing analyses for these chemicals. EPA expects that these manufacturers will make arrangements to contract these analyses out or lease time on available instruments using their own analytical support staff to perform analyses, rather than commit the funds necessary to purchase these instruments.

c. *Method sensitivity.* As EPA discussed in the proposed rule a chief concern in using any analytical method is the ability to achieve the desired level of detection/quantitation.

Comment 32: There is a definite possibility of decreasing analytic sensitivity as the analyses for the more highly substituted HDDs/HDFs are attempted. There are three reasons for this predicted loss in sensitivity: (1) The additional halogens will result in lower volatility and thus greater tendency for the compound to either adsorb or find cold sites in the column, thereby preventing elution or detection; (2) the mass spectrometer will experience a loss in sensitivity as the degree of halogenation of a congener increases, because the mass spectrometer detects molecules, rather than grams of substance. Thus, higher halogenated congeners, having fewer molecules than lower halogenated congeners, will be more difficult to detect and quantify; (3) a considerable additional loss in sensitivity (40 to 50 percent) can be expected in going from tetra to hepta

halogenated congeners because. in the case of the tetra halogenated congeners. 3 major molecular ions carry approximately 38 percent of the ion current. while in the hepta halogenated congener. 6 major molecular ions carry 23 percent of the ion current. These 3 factors can be expected to result in a loss of 50 percent analytical sensitivity in going from the tetra to the hepta halogenated congeners. (CMA p. 28).

Response to Comment 32: EPA did. in fact. consider this situation. and generally agrees with this comment on the loss of analytical sensitivity. However. LOQs have been adjusted based on toxicity of the congeners relative to the toxicity of 2.3.7.8-TCDD. This adjustment has allowed the LOQ for the heptahalogenated dioxins to rise to 100 ppb. 3 orders of magnitude less sensitive than that proposed. The LOQ for all congeners higher than tetra have been adjusted so that all are less sensitive than the 0.1 ppb and 1 ppb proposed for HDDs and HDFs respectively. These adjusted LOQs should more than compensate for the predicted loss of analytical sensitivity for the higher halogenated congeners. since the loss of analytical sensitivity from tetra- to heptahalogenated is only 50 percent. and the adjusted LOQs offer a level 3 orders of magnitude higher.

d. *Quality assurance/quality control (QA/QC) procedures.* In the proposed rule. EPA specified QA/QC requirements. including reproduceability of ±10 percent for at least 2 analyses of the same isotopically labeled HDDs/HDFs spiked to a concentration of the LOQ. and determination of the LOQ by recovery within 70 to 130 percent of the amount spiked for the internal calibration standard which has run through the entire chemical analysis. Otherwise documented corrective actions must be taken and the sample set must be rerun.

Comment 33: EPA has set QA/QC requirements that are far too stringent. Crummet et al. reported in their review of a human adipose study (Ref. 7) that 8 of the world's most experienced laboratories in HDD/HDF analysis reported highly variable results (e.g., more than 50 percent higher or lower than background and spiked levels). Recovery of spiked samples ranged from 27 to 100 percent. Crummet et al. also found that. although interlaboratory agreement is good for experimental work. many values still differ by 100 percent or more. even in matrices (tissue) that are not nearly so difficult to extract or cleanup as chemical product samples. Experienced laboratories. Crummet observes. have not achieved reproducible spiked sample results "within ±10 percent of each other." and recoveries "within 70 to 130 percent of the amount spiked." as EPA specified. and such an expectation on replicate samples at the LOQ specified is not scientifically sound. Analytical chemists always strive for narrow limits but recognize that this cannot be achieved unless they are operating orders of magnitude above the LOQ since that value is defined as the limit where they can first assign a legitimate quantitative number to the concentration. The generally accepted lower limit of recovery has been 50 percent and changing this percentage of required recovery could greatly increase the protocol development and the analysis costs." (Dow p. 15–20 CMA p. 30).

Response to Comment 33: EPA agrees that the reproducibility and recovery requirements are overly stringent for the LOQs specified. and. based on the observations outlined above. will accept an adjustment in precision to ±20 percent. and an adjustment in recovery to 50 to 150 percent. The internal standards added at initial sample preparation are subjected to each phase of extraction. separation and cleanup as experienced by the native HDDs/HDFs which may be present in the sample. Thus. the final quantitation using the ratio of responses of the native HDD/HDF to the internal standard pairs compensates for the recovery through the method.

e. *Analytical standards.* In specifying HRGC/HRMS to perform the analysis in the proposed rule. several possible methods of quantitation were examined. based on analytical standards of 2.3.7.8-HDD/HDF compounds in concentrations similar to the concentration range of interest (0.1 ppb for 2.3.7.8-HDDs and 1.0 ppb for 2.3.7.8-HDFs) found in chemical products to be tested.

Quantitation using internal standards was selected as the preferred method in the proposed rule. because the use of internal standards can provide continuous monitoring of extraction efficiency and method precision in the analysis of actual product samples; thus the internal standards may provide information on matrix effects. Since the HDD and HDF compounds of greatest concern are those substituted at the 2.3.7.8 positions. EPA specified that these compounds (isotopically labeled) be used as reference standards in the proposed rule. These analytic standards are expected to be available from at least one manufacturer at the time this rule becomes effective. (See comments to the proposed rule submitted by Cambridge Isotope Laboratories).

Comment 34: CMA's review of the availability of standards required indicates only 1 of the required 30 brominated and 23 of the 30 required chlorinated standards are available. (CMA p. 38).

Response to Comment 34: EPA relies on comments submitted by Cambridge Isotope Laboratories in which its president. Dr. Joel Bradley. states that all chlorinated and brominated standards required in the proposed rule will be available by the time this rule is promulgated. with the possible exception of 1.2.3.4.6.7.8- and 1.2.3.4.7.8.9-HpBDF.

3. *Period for submission of test data.* EPA proposed that manufacturers subject to the testing requirements of this rule submit protocols developed for the analytical methodology within 6 months after promulgation of a final rule. and that test results for the listed chemicals be submitted no later than 1 year after EPA review of protocols for analytical methodology.

Comment 35: EPA should extend the time for completing the analyses for all chemicals. and analyses for brominated congeners should be extended even more. All previous work has been done on chlorinated compounds. and even that is state-of-the-art. In addition. the brominated HDDs/HDFs are expected to present additional problems such as chemical reactivity and heat and light instability. (CMA p. 45: Dow p. 13: Ethyl p.1: Vulcan p.1: Ameribrom p.1: Great Lakes p.1).

Response to Comment 35: EPA agrees that the time should be extended for development of protocols. since most of the methods development work will be done during that period. However. the time allowed for actual analysis. once the method has been developed. can be decreased from 1 year to 6 months. Further. EPA agrees that additional time is needed to adapt and develop methods for analysis of the brominated congeners. since very little work has been done in this area. Therefore. EPA has adjusted the schedule for development of methods and submission of protocols to 1 year for predominantly chlorinated compounds and 2 years for predominantly brominated compounds. Time for analysis has been adjusted to 6 months after EPA review of the protocol.

Comment 36: EPA should require tiered testing within the testing scheme for brominated chemicals so that brominated diphenyl ethers are tested before brominated phenolics and their derivatives. and so that Tetrabromobisphenol-A is tested before any of its derivatives. The rationale for this scheme is that the more difficult

analytical problems posed by the brominated diphenyl ethers will facilitate the development of an analytical method for the phenolics, and that Tetrabromobisphenol-A as the parent compound should be tested before its derivatives, since the only source of HDDs/HDFs in the derivatives would be from the parent compound. (Great Lakes pp. 46 thru 50).

Response to Comment 36: EPA agrees with the expected difficulty of testing diphenyl ethers, since the molecule is so similar to the HDF molecule that separation of the matrix will be difficult. However, the logic of testing the more difficult compound first seems reversed. In any case, the decision about which compounds to test first is an internal management decision to be made by each manufacturer depending on the circumstances. EPA has added an extra year to the timetable for testing of brominated compounds, and believes each manufacturer should determine testing priorities within that time.

EPA listed the derivatives of Tetrabromobisphenol-A because the contamination is expected to result from manufacturing conditions the same as or similar to those for the parent compound, not as a result of a contaminated feedstock, as would be the case if the contamination is expected to result from the parent compound. However, EPA will leave testing order or priority up to each manufacturer.

4. *Persons required to test.* Persons required to test has been fully discussed in the preamble to the proposed rule under Unit IV.B.4. (50 FR 51803, Dec. 19, 1985). EPA has found that there is insufficient data and experience upon which to determine or reasonably predict the effects of the manufacture, processing, distribution in commerce, use, and disposal of the chemicals subject to the testing requirements of this rule. Therefore, in accordance with section 4(b)(3)(B) of TSCA, manufacturers and processors are responsible for testing.

It is expected that in all cases subject to this rule, testing will be performed by each of the manufacturers on the most appropriate grade of the substance they produce, and that part of the cost of testing will be passed on to the processors through the pricing mechanism, thereby enabling them to share in the costs of testing. Section 4(c) of TSCA permits a manufacturer to obtain exemptions from testing if the substance it produces is equivalent to a test substance and testing the substance would result in generation of duplicative data. A manufacturer will not be permitted to obtain an exemption based upon another manufacturer's testing unless it can demonstrate that the substance it produces is equivalent to the substance being tested. A manufacturer must designate the test substance it believes is equivalent to the substance it produces and submit detailed, complete process and reaction condition data to substantiate its claims of equivalence.

Processors will be called upon to sponsor testing only if manufacturers fail to do so; however, in some cases processors may be required to provide reimbursement directly to those sponsoring this testing. If the manufacturer does not submit a letter of intent to perform testing within the 45-day period, EPA will issue 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 testing and that current processors will have 45 days to submit either a letter of intent to perform the test or an exemption application for such testing. Each processor who submits a letter of intent to perform testing will be obligated to submit a proposed study plan and, ultimately, to perform testing. If processors are required to sponsor testing, they may apply for exemptions from testing by submitting process data to demonstrate equivalence.

If no manufacturer or processor submits a letter of intent to perform testing, EPA will notify all manufacturers and processors, either by notice in the **Federal Register** or by letter, 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 required testing.

5. *Chemical screening methods.* In the preamble to the proposed rule, EPA noted that all chemical screening methods investigated were either as expensive as the required testing or were unreliable. EPA requested comments and information on the availability of a screening method which could be used to determine whether the full-scale analysis would be necessary.

Comment 37: EPA should allow a manufacturer to test for the most likely congener to form based on predictive reaction chemistry, and if that congener was not quantifiable, discontinue further testing. Dow cited an analytical effort in which reaction chemistry predicted that dichloro dioxins would predominate, and analysis ratified that prediction. (Dow p. 10; April 22 Transcript pp. 86 and 87).

Response to Comment 37: EPA finds three drawbacks to this approach. First, the predicted congener may or may not be formed according to the most probable reaction pathway. For example, in the case of pentachlorophenol, reaction conditions favorable to the formation of dioxin should yield a predominance of octachlorodioxins as reaction products; yet a large number of lower chlorinated dioxins are routinely observed as well. Additionally, under this scheme, a significant level of a congener different from that predicted or analyzed for would never be measured or reported. Finally, any chemical subjected to this type of screen would have to undergo extraction and cleanup identical to that required for the required HDD/HDF analysis. Because extraction and cleanup comprise most of the testing cost for a given sample, very little economic advantage would be realized by adopting such a screen.

Comment 38: EPA should allow a screen for total dioxins at a level of 0.1 ppb, and, if none were found, the chemical could be considered "clean," with no further analyses necessary.

Response to Comment 38: EPA finds this approach acceptable in terms of evaluating the chemical from a potential health risk standpoint, but EPA did not propose this screen, believing it unacceptable to manufacturers in degree of difficulty and cost of the method. As noted above in the Dow comment, the chemical subjected to such a screen would necessarily undergo extraction and cleanup procedures identical to a sample prepared for the standard HDD/HDF analytical methods now in use; thus EPA believes no substantial cost saving would be realized, and the manufacturer could incur large additional costs to test for congeners if the screen resulted in HDDs/HDFs above the level of 0.1 ppb.

EPA has not found a perfect chemical screening method which is acceptable both in terms of sensitivity and cost effectiveness when compared to the analytical approach outlined in this final rule. However, EPA will consider results from a screen for total HDDs/HDFs at a level of 0.1 ppb for HDDs/HDFs, or 0.1 ppb for HDDs and 1.0 ppb for HDFs, for which a protocol must be submitted and reviewed by EPA. The screen must be carried out using acceptable methods as described in the protocol reviewed by EPA.

Should EPA identify a chemical screening method which it believes suitable both in terms of sensitivity and cost, EPA may amend this rule to permit submission of results from that method.

Since the publication of the proposed rule, EPA has further investigated the

possibility of chemical screens and has identified the following chemical screening methods:

a. *Derivative testing.* This method relies on the conversion of lower halogenated dioxin or furan compounds to the octahalogenated configuration and the analysis for the presence of these octahalogenated species. At present, there is disagreement among industry and academia as to the efficacy and validity of this method as a predictor or screen for higher substituted PHDDs/PHDFs, primarily because of the unresolved issue of yield (e.g., to what degree the conversion from the lower halogenated to the octahalogenated configuration takes place). At least one investigator, however, has had limited success in converting lower substituted PCBs to fully substituted octachlorinated biphenyl (Ref. 36).

b. *Reverse phase chromatography with UV detector.* A calculated LOQ of 0.167 ppb has been achieved on internal standards (5ng/30g) of isotopically labeled 2,3,7,8-TCDD (Ref. 36). EPA has not yet determined whether this method is applicable as a chemical screen in terms of reliability or laboratory reproducibility on a consistent basis.

c. *Short column GC with halogen detector.* The halogen detector is a very sensitive instrument which relies on electron capture or conductivity detection to calculate the amount of halogenated species. The short column GC can be used to separate other interferences which are normally not able to be isolated using standard methods for sample extraction and cleanup. However, one investigator reported that in using this method in analyzing pentachlorophenol, the chlorinated diphenyl oxide almost never separated, often giving false positives in the analysis.

d. *Total GC separation with MS as detector.* This method relies on the separation of the various PHDD/PHDF homologs using gas chromatography, after which mass spectrometry is used to detect the individual homolog. This is made possible by defining the "window of separation" for each homolog.

e. *Bioanalytical screening methods.* In the preamble to the proposed rule, EPA noted that it had investigated radioimmunoassay (Refs. 1 and 23); arylhydrocarbon hydroxylase (AHH)-induction (Refs. 6 and 28); cytosol receptor assay (Ref. 2); an early life stage bioassay (Ref. 17) and an *in vitro* keratinization assay (Ref. 20). As outlined in the proposed rule, the primary advantages of the radioimmunoassay, the AHH and the cytosol receptor assay are relatively low cost and rapidity. The disadvantage of these techniques in general is that they do not necessarily respond to specific isomers of HDDs and HDFs; they respond to other compounds such as halogenated biphenyls, azobenzenes, and nonhalogenated polynuclear aromatic hydrocarbons, and each technique is less sensitive than available mechanical analytical methods. The *in vitro* keratinization or E.L.S. bioassays more recently have provided possibly more specificity for determining the presence of 2,3,7,8-HDDs/HDFs. Both techniques have been demonstrated to give roughly comparable results with HRGC/MS analysis of total PCDDs and PCDFs in a PCB fire soot (Ref. 16), and fly ash from a municipal incinerator (Ref. 17).

It is important to note that each of the bioassay techniques is most sensitive to the presence of 2,3,7,8-TCDD as opposed to other HDDs/HDFs. It is speculated that the relative response to other HDDs and HDFs might be dependent on halogen substitution in the 2,3,7,8 positions and ultimately to the toxic potential of the compound. It is also important to note that the range of compounds evaluated with each of these bioassay techniques is somewhat limited. EPA believes that evaluation of commercial products for the presence of HDDs and HDFs with any of these bioassay techniques could be a valuable screening tool, particularly in terms of time and resources necessary for the chemical preparation and instrumental analyses of these chemicals. At this time, EPA does not have sufficient data to determine the adequacy of these bioanalytical techniques and whether they are sensitive enough to achieve the level and specificity of detection necessary to quantitate 2,3,7,8-HDDs/HDFs at very low levels. Additionally, the economic advantage of these methods relies in large measure on the number of samples run; only in large (bulk) analyses would significant savings in cost be realized over other recommended methods such as GC/MS, etc. For such bulk sample analyses, the method also must be standardized in terms of reproducibility and reliability; it must be available for routine analyses on a large scale. These methods, while currently undergoing further development, are not yet acceptable for screening purposes.

V. Economic Analysis of Final Rule

A. Estimated Cost of Testing Program Under Section 4(a)(1)(A)

This portion of the preamble presents EPA's estimate of the total cost of this rule and reviews the potential marketplace effects identified by EPA. The estimated costs and expected impacts are discussed in detail in the economic analysis prepared in support of this rulemaking. Much of the information reviewed in the economic analysis is CBI and is not available for public review. This analysis is in the rulemaking record for this rule. A non-CBI version of the economic analysis has been prepared and is available for public review. Estimated costs and expected economic impacts of the rulemaking are summarized below.

Information incorporated in the economic analysis was found in a variety of sources; a detailed account of the specific information sources used in the economic analysis is available in the public record. In brief, EPA contractors initially provided estimates of the production volumes, process, and uses of each chemical, as well as the identity of each manufacturing or importing firm. These data were verified by review of the available technical literature, and by direct contact between EPA and representatives of the manufacturing firms. In those cases where information was not available directly from industry sources or from the literature, estimates were made from the best available information. Much of the information submitted to the EPA from manufacturers was claimed confidential.

Assessment of the potential for significant adverse economic effects on the chemical industry as a direct result of this rule was performed using EPA's standard method for measuring impacts of TSCA section 4 testing rules. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of each chemical: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If there is no indication of significant adverse effect for an individual chemical, no further economic analysis is performed; however, if a potential for significant adverse impact is identified for a specific chemical, a more comprehensive and detailed analysis is conducted which more precisely reviews the magnitude and distribution of expected impact on that chemical. In keeping with the worst-case cost methodology incorporated in the economic analysis, at each point in the analysis where a wide range of costs can be justified, a highest cost scenario has been assumed so as not to

underestimate the potential burden borne by the firms subject to testing.

Of the 32 chemicals subject to this testing rule, 12 have been identified as chemicals currently being manufactured or imported. Fourteen firms have been identified as manufacturers or importers of one or more of these twelve chemicals. Because each manufacturer uses a unique production process and unique equipment and raw materials which could lead to contamination of the chemical by HDDs/HDFs, each manufacturer/importer is required to test its own chemical product. In total, 32 unique chemical products have been identified by EPA as subject to this testing rule.

The total cost for performing the requisite testing on the 32 chemical products is estimated at $2.37 million. This estimate of the total cost of the testing program is composed of three elements: development of analytical methods for the determination of HDDs/HDFs in the subject chemicals, synthesis of analytic standards, and the analysis of each sample.

1. *Methods Development.* Testing for the specified HDD/HDF congeners in commercial chemical products will require that methodologies for preparing and testing samples be developed for each chemical. Testing firms are free to use the most cost effective method of clean-up and analysis that they can identify to meet the test requirements and QA/QC requirements. EPA believes that it is in the best interest of the testing firms to coordinate their method development activities in order to minimize total cost.

EPA estimates that the upper bound cost for methods development for the testing specified in this rule is $1.25 million. In the economic analysis for the proposed rule, EPA estimated methods development costs at $600,000. In comments to the proposed rule, several commenters questioned this cost estimate, including Great Lakes Chemical Company, which claimed that the actual methods development costs would be equivalent to 10 person-years of analytic chemist labor valued at $125,000 per person-year. The total cost for methods development would then be $1.25 million. Due to the difficulty of projecting costs prior to the performance of the methods development, EPA has adopted this estimate as a reasonable upper bound.

2. *Synthesis of analytical standards.* To conduct the sample analyses, any requisite analytical standards which are not available will have to be manufactured. The acquisition cost for commercially available standards are included in the cost of each sample analysis, but costs for synthesizing and producing standards that are not commercially available upon the promulgation of the rule are a unique cost of the rule. EPA estimates that there will be no unique cost for analytic standard manufacture due to this rule.

In the economic analysis supporting the proposed rule, the cost for analytic standards was estimated at $182,000. This estimate was based upon the manufacture of 18 standards which were unavailable at that time. In comments to the proposed rule, one commenter, Cambridge Isotope Laboratories (CIL), responded that CIL was in the process of manufacturing for commercial sale the 18 unavailable standards. Subsequent communications between EPA and CIL have demonstrated to the satisfaction of EPA that the standards are indeed available at this time. Therefore, costs for the synthesis of analytical standards due to this rule are estimated at $0.

Other commenters to the proposed rule commented that the costs for analytic standard synthesis were underestimated because EPA had not taken into account additional (non 2,3,7,8-substituted) standards which would be required to conduct the sample analyses. EPA has concluded that there will be no additional cost because the additional standards are not necessary to conduct the sample analyses.

3. *Sample analyses.* The total cost for sample analysis is estimated at approximately $1.12 million. Each sample analysis is expected to cost from $2,000 to $5,000, and each chemical product may be analyzed up to 7 times for an upper bound testing cost of $35,000 per chemical product. An estimated 14 manufacturers will test an estimated 32 sample sets for approximately $1.12 million.

Costs for sample analysis are lower than the sample analysis costs estimated in the economic analysis for the proposed rule. Two factors account for the reduced cost estimate. The number of chemicals subject to testing is smaller—12 commercially available chemicals in the final rule as opposed to the 14 commercially available chemicals included in the proposed rule. Secondly, additional information on manufacturers/importers gathered in the interim following the publication of the proposed rule has shown that some firms originally identified as manufacturers or importers of some chemicals are not current manufacturers or importers.

B. Anticipated Economic Impact Under Section 4(a)(1)(A)

A review of the costs allocated to each manufacturer and chemical indicates that the probability of significant adverse economic impact for seven chemicals is very low. However, the cost analysis indicates potential for significant adverse economic impact for the five remaining chemicals. These five chemicals were therefore reviewed in greater detail. After further investigation, EPA has determined that the likelihood of adverse economic impact of three of the five chemicals is low. Each of the five chemicals is discussed below. Specific costs allocated to each chemical and the impact level calculated for each chemical are not reported here, in most cases, because the data used in the cost calculations are CBI.

1. *Tetrabromobisphenol-A Diacrylate.* The calculated impact level for Tetrabromobisphenol-A (TBBPA) diacrylate indicates that the probability of adverse economic impact is very high. Further investigation into the market characteristics of this chemical indicates a high likelihood that the chemical will be withdrawn from the market by its manufacturer, ARCO Specialty Chemicals. ARCO did not submit comments to the proposed rule; however, direct contact between EPA and a representative from the manufacturer verified that TBBPA diacrylate is a low volume specialty flame retardant which has been manufactured on a developmental basis only. The annualized allocated test costs for TBBPA diacrylate are confidential, but are believed to be higher than the manufacturer's annual revenue from the product. Given these costs, Horsehead Industries, which recently acquired ARCO Specialty Chemicals, will probably cease manufacture and distribution of the chemical if faced with the testing costs.

2. *2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione (Chloranil).* The estimated costs allocated to the chemical chloranil raise the probability of adverse economic impact. Further investigation of the market characteristics of chloranil indicates that firms importing small amounts of chloranil may cease importation (similarly, firms which have in the past imported chloranil may be prevented from re-entering the market) due to the testing costs. One or more firms importing chloranil in significantly higher volumes will be able to provide any necessary supply displaced from the other firms.

Six firms are believed to be current or recent importers of chloranil; however, only one or two of the importing firms are also chloranil manufacturers. The other importers purchase their supply of chloranil directly from the manufacturing firm(s). Due to the small volumes believed to be imported by the non-manufacturing firms, the annualized allocated test costs represent a substantial proportion of the revenue attributable to chloranil. Therefore, it is anticipated that the non-manufacturing importers will exit the market (or avoid re-entering the market) rather than contribute to the testing program. The firm(s) which are both manufacturers and importers will then provide the additional supply of chloranil and pay for a greater portion of the testing costs.

The importing firms which may be displaced from the market are among the smallest firms subject to this rulemaking. However, these firms import relatively small quantities of chloranil, and none are financially dependent upon chloranil. Withdrawing from the market for chloranil (or remaining out of the market) will not adversely affect any of the non-manufacturing importers.

3. *Tetrabromobisphenol-A-Bis-2,3 dibromopropylether, Tetrabromobisphenol-A-Bisethoxylate, and Allylether of Tetrabromobisphenol-A.* The estimated testing costs allocated to each of these three chemicals indicated the possibility of significant adverse impact. Additional investigation into the market characteristics of each chemical indicates that the probability of significant adverse impact is low. Much of the information upon which this conclusion is based is CBI and is therefore not available for public review. In general, this conclusion is based upon the following observations: (1) Each of these three chemicals is a brominated flame retardant. Demand for brominated flame retardants has expanded rapidly, and market expectations for brominated flame retardants are optimistic; (2) EPA believes that demand for each of these chemicals is relatively insensitive to changes in price because of a lack of substitutes which are comparable in terms of price and/or performance; and (3) The structure of the markets for each chemical supports the conclusion that the testing costs will not cause a significant adverse impact.

C. Testing Costs as a Barrier to Market Entry

After this rule takes effect, any firm wishing to initiate manufacture of any of the 32 subject chemicals will incur costs for methods development and sample analysis. These costs will serve as a barrier to entry into the markets for these chemicals. This effect will be most significant for firms wishing to initiate production or importation of only a small volume of one of the subject chemicals. However, the regulation provides an opportunity for obtaining waivers from testing in certain circumstances.

D. Costs of Reporting Under Section 8

1. *Section 8(a):* The costs of reporting under section 8(a) are minimal. Under the section 8(a) rule, submission of four different sets of reports are specified: (1) Submission of production process and reaction conditions for chemicals identified as precursors; (2) submission of certain existing data for the 32 chemicals listed for testing in this rule; (3) production volume, process and reaction conditions, use, exposure, and disposal data for chemicals testing positive for HDDs/HDFs; and (4) process and reaction conditions on chemicals testing negative for HDDs/HDFs may be required by EPA if any other manufacturer of the same chemical discovers HDD/HDF contamination.

Three unique sets of information will be submitted for the four reporting categories outlined above. The first set will be reported by firms manufacturing or importing a chemical which tests positive for HDDs/HDFs. These firms must report to EPA on production volume, use, exposure, disposal, and process conditions under which their products are manufactured. The second set consists of firms manufacturing or importing any of the 32 chemicals subject to testing for which quantitative analyses for HDDs/HDFs has already been conducted. These firms will be required to report test results and test protocols, and the firms will fall into the first set if the results submitted indicate HDD/HDF contamination. The third set is composed of processors of precursor chemicals and manufacturers/importers of chemicals free from HDD/HDF contamination when at least one manufacturer or importer of the same chemical tests positive for HDD/HDF contamination. Processors of precursor chemicals will be required to submit data on process and reaction conditions for their chemical. If manufacturers/importers of chemicals free from HDD/HDF contamination are required to report, that determination will be made in a rulemaking following the receipt and evaluation of the testing data.

Reporting on previously conducted tests should cost reporting firms from $273 to $546 for each chemical previously tested (Ref. 37). Those costs include from 2 to 4 hours of managerial labor to review the rule, 4 to 8 hours technical labor to collect the test methodology data, and 2 to 4 h clerical labor. Any firms report positive identification of HDD/HDF contamination will also be subject t costs detailed below.

Firms subject to reporting due to positive results indicating contamin must report the following informati chemical production volume, use, process and reaction conditions, disposal, and exposure data. This information should be submitted on EPA form printed under § 766.64. It estimated that completion of this fo will require from 40 to 80 hours fron industrial chemist and 1 process engineer (Ref. 37). In addition, 4 to 8 hours of managerial time will be required for initial review of the rul legal review of the rule, and final re of the form. Four to 8 hours of cleric time will be required for completior the form. For firms reporting on mul chemicals, managerial and clerical may be a one time cost. The direct c of filing the form will range from $1. to $3,214 per chemical (Ref. 37).

Firms required to report because manufacture a chemical made from precursor chemical listed in this rul must provide their production and process and reaction conditions direct costs of filing the form w the range of $944 to $2,551. The co based on the contribution of from 2 60 hours of labor from 1 industrial chemist and 1 process engineer, plu managerial labor to review the information and clerical labor to pr the submission (Ref. 37).

2. *Section 8(c):* Submission of tw of adverse reaction conditions are specified in this rule. Any reports o significant adverse reactions to HD HDFs must be submitted by manufacturers of any of the 32 chemicals listed for testing in this r Once the testing has been conduct those firms finding a positive test r indicating contamination by HDDs HDFs for any of the 32 chemicals w subject to the second part of the se 8(c) Data Call-In for reports of significant adverse reactions to the chemicals testing positive for HDD contamination.

Of the 32 chemicals subject to th rule, an indeterminate number may identified as contaminated with HI HDFs. Without knowing the numbe firms which currently maintain rec of significant adverse reaction due HDD/HDF contamination and the number of contaminated chemi precise costs of the section 8(c) requirement cannot be determi

costs for any individual firm required to report will be composed of the following elements: review of the rule, file search for records subject to reporting, review of any records identified for CBI, costs for copying identified records, and the cost for submission to EPA.

Both fixed and variable costs will be incurred by each firm manufacturing or importing a chemical identified as contaminated with HDDs/HDFs. It is estimated that for each firm reporting, 1 to 2 hours of managerial labor will be expended to review this rule, and 3 to 6 hours of technical labor will be expended to search files for reports of significant adverse reactions. For each such report located, the reporting firm will incur clerical costs to reproduce and prepare the document for submission and additional managerial costs to review the report for CBI. The direct costs for each firm subject to this Data Call-In will be from $150 to $300, plus $80 per 10 page report submitted (Ref. 38).

Every firm subject to the initial section 8(c) requirement will incur costs to review the rule and conduct a file search. If any reports are located, preparation and review of the response to the Agency will entail additional costs. Firms manufacturing or importing chemicals which test positive for HDD/HDF contamination will also incur costs for review of the rule, file search, an response to the Agency. Though the firms subject to the second part of the section 8(c) requirement have reviewed the rule previously to respond to the first reporting requirement, it is assumed that rule review and file search will be repeated because of the time lag between initial response and completion of testing. The maximum total fixed cost for the initial response will be from $2,260 to $4,520 plus $80 per report of a significant adverse reaction (Ref. 38). Total cost of the section 8(c) requirement for contaminated chemicals will depend upon the number of contaminated chemicals.

3. *Section 8(d):* Submission of two sets of unpublished health and safety studies are specified in the rule. Any unpublished health and safety studies for HDDs/HDFs must be submitted by manufacturers of any of the listed chemicals. Once testing has been conducted, firms finding positive results of HDD/HDF contamination will be subject to this section 8(d) rule. Of the chemicals subject to this rule, an indeterminate number may be contaminated. Without knowing the number contaminated, the precise costs of the call-in cannot be determined.

Companies subject to this rule must conduct file searches, copy the studies, list studies in progress or known but not in posession of the respondent, and review the studies for CBI. Both fixed and variable costs will be incurred by each firm manufacturing or importing a chemical identified as contaminated. It is estimated that for each reporting firm, 1 to 2 hours of managerial labor will be expended for initial review of this rule, and 3 to 6 hours of technical labor will be expended to search files for unpublished health and safety studies. Compiling and transcribing lists of studies should take no more than 1 additional hour of clerical labor. For each study located, the reporting firm will incur additional clerical costs to reproduce and prepare the document for submission, and additional managerial costs to review the report for CBI. The direct costs for each firm subject to this section 8(d) requirement will be from $170 to $320, plus $80 per 15 page study submitted (Ref. 39). Additional costs may be incurred for submission of on-going or newly initiated studies.

Every firm subject to the initial reporting of unpublished health and safety studies will incur costs to review the rule and conduct a file search. If any reports are located, preparation and review of the response to EPA will entail additional costs. Firms manufacturing or importing chemicals testing positive for HDD/HDF contamination will also incur costs for review of the rule, file search, and response to the Agency. Firms subject to the second part of the section 8(d) reporting will have reviewed the rule previously to respond to the first requirement, but it is assumed that rule review and file search will be repeated because of the time lag between initial response and test completion.

The maximum total fixed cost for the initial response will be from $2,540 to $4,810 plus $80 per study submitted (Ref. 39). Total cost of the section 8(d) requirements for HDD/HDF contaminated chemicals will depend upon the number of chemicals testing positive for contamination.

VI. Availability of Facilities

Section 4(b)(1)(C) of TSCA requires that in the development of a test rule the Administrator consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Pursuant to this requirement, EPA conducted a survey of commercial analytic testing laboratories to determine the availability of facilities, equipment, and personnel necessary to perform the tests outlined in this final rule (Ref. 41).

A list of 57 laboratories was compiled, consisting of 17 laboratories with current contracts under the EPA's Superfund Contract Laboratory Program, and 40 laboratories from the 1984 Directory of the American Council of Independent Laboratories. Twenty-five laboratories (the 17 EPA contract labs and 8 others chosen at random) were contacted by telephone.

The laboratory capacity survey identified a number of commercial analytical testing laboratories with high resolution GC/MS systems and experience using these systems, though not necessarily experience with detecting HDDs/HDFs in commercial chemical products. In written comments to the proposed rule and in a subsequent public meeting, industry representatives stated that testing 14 chemicals in 1 year would strain the capacity of qualified testing laboratories. EPA considered these comments, and in response, is extending the proposed time limit for submission of test results for the 10 brominated chemicals by 1 year.

Information gathered in support of this final rule shows a reduced likelihood of straining the capacity of qualified testing laboratories to perform the requisite analyses. In the proposed rule, 14 chemicals were included in the list of commercial chemicals subject to testing requirements. EPA projected that 54 sets of samples would require testing. For this final rule, only 12 commercial chemicals are subject to testing, and EPA projects that 32 sets of samples will be tested.

In addition to the commercial laboratories identified in the laboratory capacity survey, CMA has submitted a list of qualified laboratories in its comments on the replicability of testing results. Supplemented by non-commercial laboratories (i.e., universities and in-house laboratories of major chemical companies) such as those identified by CMA, and given an extra year to complete the analyses on approximately one-half the number of samples projected in the proposed rule, testing should proceed without any restrictions due to capacity availability.

VII. Section 8 Reporting

A. Reporting Under Section 8(a)

Under section 8(a)(1)(A) of TSCA, EPA may require chemical manufacturers and processors to maintain such records and submit such reports as the Agency may reasonably require. The information to be submitted is that which is known to or is reasonably ascertainable by the person making the report (section 8(a)(2)).

Further, section 8(a)(1)(A) generally exempts small manufacturers and processors from recordkeeping and reporting requirements, except in certain limited circumstances. Of particular relevance to this rule, section 8(a)(3)(A)(ii) authorizes EPA to override the small manufacturer exemption for chemicals subject to a rule proposed or promulgated under section 4 of TSCA. Section 8(a)(2) also notes that to the extent feasible, EPA should not require unnecessary or duplicative reporting.

Under section 8(a) of TSCA, EPA proposed to require manufacturers of chemicals listed for testing to submit results of any testing, performed prior to the effective date of this rule, which shows concentrations of any HDDs/HDFs in any of the chemicals listed for testing. EPA also proposed to require under TSCA section 8(a) that manufacturers of any chemical in which a positive test result is reported, report production volume, process and reaction conditions, exposure, use, and disposal data on the EPA Form 7910-51, printed under § 766.30(e)(5) in the proposed rule. Also under TSCA section 8(a), EPA proposed to require manufacturers (except small manufacturers as defined under § 766.3) of any chemical manufactured using any of the chemicals listed as precursors to report production volume, process and reaction conditions, use, exposure, and disposal data for each such chemical, using the Dioxin/Furan Report Form.

Comment 39: EPA should not require extensive production and process information on precursor chemicals and should set a level of production below which information need not be submitted. The reporting required in the proposal is excessive (Kodak p. 2).

Response to Comment 39: EPA partially agrees with this comment, and has set the level of production suggested by Kodak below which information need not be submitted. EPA disagrees about the need for production and process information; only with this data can EPA determine whether other chemicals should be listed for testing. To lessen reporting requirements for chemicals made from precursors, EPA has eliminated all reporting of production volume, use, exposure, and disposal data, which is not needed for the decision to require testing. EPA's intent is to discover whether any additional chemicals are manufactured under conditions that could produce HDDs/HDFs. For this purpose, only process and reaction condition data are needed.

Since EPA has allowed an exemption from testing for chemicals produced in annual quantities of 100 kilograms or less for research and development purposes, it is reasonable to allow the same exemption for chemicals produced from precursor chemicals. Such chemicals would not become testing candidates. Therefore, a responsible official from any chemical manufacturer may certify that a chemical produced from a listed precursor is produced in quantities of 100 kilograms or less per year, and used only for research and development purposes, in lieu of submitting process and reaction condition information for that chemical.

Comment 40: EPA should specify the conditions which favor HDD/HDF formation and require reporting only in situations where contamination is likely, to reduce the reporting burden. (Kodak p. 2; p. 1 in comment to proposed amendment adding additional precursors; EDF p. 3 in comments to proposed amendment adding additional precursors; CMA p. 8 in comments to proposed amendment adding additional precursors).

Response to Comment 40: These conditions are set out and discussed in the support document (Ref. 43) used by EPA to select chemicals for testing. These conditions have been applied to confidential process and reaction data sent to EPA by several manufacturers seeking to convince EPA that these conditions are not present during the manufacturing process for their chemicals. In reviewing the process data submitted, EPA discovered several borderline decision points, and made decisions based not on a single factor, such as heat, but on a combination of factors, including duration of the process, composition of the reaction vessel, presence of oxygen, etc. If EPA set out specific temperature, pressure, and alkalinity conditions, it could miss a large body of data that would be borderline, and for which non-submission could be justified. Therefore, EPA prefers to make decisions on whether there are additional chemicals which are candidates for testing. EPA has eliminated most of the reporting requirements and kept only the process and reaction condition data needed to determine, on a case-by-case basis, whether a chemical is manufactured under one condition or a combination of conditions that may lead to HDD/HDF contamination.

Comment 41: EPA should consider a small quantity exemption for specialty and research and development purposes for both chemicals to be tested and for precursor chemicals. A reasonable cut-off for this purpose is 100 kilograms per year. (Kodak p. 2).

Response to Comment 41: EPA agrees with the small quantity exemption for research and development portion of this comment, and has added such an exemption in this final rule. EPA believes it is not likely that a chem produced in small quantities for research and development purposes wi cause an unreasonable risk, based on the expectation that persons using such a chemical will be trained to recognize and protect against potential hazards from such chemicals. Therefore, EPA has added an exemption for both test chemicals and chemicals made from precursors which are produced in quantities of 100 kilograms or less per year, and which are used for research and development purposes. Such a determination cannot be made for specialty chemicals not used only for research and development, however, without knowing specifically how such chemicals are used and could be used.

B. Reporting Under Section 8(c) of TSC

Under section 8(c) of TSCA, EPA proposed to require manufacturers of chemicals listed for testing to submit reports of significant adverse reactions alleged to have been caused by HDDs/HDFs. EPA also proposed to require manufacturers of chemicals listed for testing to submit, 90 days after submission of a test result showing contamination by HDDs/HDFs abo the appropriate LOQ, reports of significant adverse reactions alleged t have been caused by the chemical tested. All such submissions were to follow the procedures set out in 40 CFI Part 717.

The comments received on submission of allegations of significan adverse reactions asked for clarificati of the requirements. Clarification of these requirements has been made in this final rule.

C. Reporting Under Section 8(d) of TSCA

Under section 8(d) of TSCA, EPA proposed to require any chemical manufacturers to submit health and safety studies on any HDDs/HDFs, a manufacturers of chemicals listed for testing for which contamination abov any LOQ is reported to submit, 90 day after submission of the positive test result, all health and safety studies on the tested chemical. All submissions were required to follow the procedure set out in Part 716 of this Chapter.

Comments received on reporting under section 8(d) of TSCA requested clarification of requirements. Such clarification has been made in this rule.

VIII. Relationship to Section 12(b) of TSCA

Section 12(b)(1) of TSCA provides for notification to the Administrator of any intention to export any chemical for which submission of data is required under section 4 of TSCA or section 5(b) of TSCA. The Administrator is required to notify the government of any country to which export occurs of the nature of the requirement and the availability of data submitted to the Agency for that chemical.

Regulations requiring notification to EPA of export or intended export of any chemical for which data are required under TSCA section 4 are codified at 40 CFR 707.60 through 707.75. They specify who must notify the Agency, when notification takes place, the required contents of the notice, and permission to assert a claim of confidentiality for any of the information. EPA has interpreted section 12(b) of TSCA and the regulations under 40 CFR 707.60 through 707.75 to apply at the time a rule is promulgated under section 4 of TSCA. (See 45 FR 82850, December 16, 1980). However, the regulations and statute do not specify a time when such notification requirements will cease.

Comment 42: EPA's interpretation of its regulations requires export notification at the time a testing requirement is issued under section 4 of TSCA, rather than at the time when data resulting from those requirements are available. Such notification will unfairly stigmatize a chemical, and should be delayed until testing shows levels of HDDs/HDFs above the LOQs. (CMA at pp. 46 and 47).

Response to Comment 42: EPA continues to believe that its previously published interpretation of section 12(b) and its regulations are appropriate. Notification will commence in accordance with applicable regulations. EPA's notice to foreign governments, however, will state that the Agency is only testing for potential contamination and is not imposing regulatory constraints on these chemicals. The intention of the notice will be to avoid making any statements which unfairly stigmatize the chemical. EPA has concluded that it should specify for this rule circumstances under which notification requirements under section 12(b) may be terminated for specific chemicals.

The results of the testing required under this rule will yield definite results—either they will show contamination by HDDs/HDFs or no contamination by HDDs/HDFs at the target LOQs. If contamination of a specific substance produced by a specific process is shown, it is appropriate to continue to require export notification under section 12(b) so that foreign governments can be provided with the testing results. However, if there is no contamination shown at the target LOQs for a specific substance produced by a specific process, there is no further concern for adverse health effects resulting from HDD/HDF contamination of that substance and, thus, no reason for the manufacturer to continue notification to EPA, or for EPA to continue to notify the foreign governments about that manufacturer's exports.

Accordingly, EPA has concluded that it is appropriate to amend its section 12(b) rule to end notification requirements in such situations. The amendment to 40 CFR Part 707 adding a new § 707.72 provides that when test results showing that a specific substance produced by a specific process has no HDDs/HDFs above the target LOQs are submitted to EPA under this test rule, export notification to EPA is no longer required of any person who is exporting that substance produced by that process.

IX. Compliance and Enforcement

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)(A) 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: "(A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records required by this Act or a rule" 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(a) 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 inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for chemicals listed under § 766.20. These inspections may be conducted to verify that testing has begun, schedules are being met, reports accurately reflect the underlying raw data and interpretations and evaluations, and to determine compliance with TSCA Good Laboratory Practices (GLP) standards and the test standards established in the rule.

EPA's authority to inspect a testing facility is also derived 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 to include 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 which may be calculated as if they 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 for each violation with each day of operation in violation constituting a separate violation. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 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.

X. Rulemaking Record

EPA has established a record for this rulemaking (OPTS-83002). This record includes basic information considered by the Agency in developing this final rule and appropriate Federal Register notices.

This record includes the following kinds of information:

1. **Federal Register** notices pertaining to this rule.
2. Study of availability of test facilities and personnel.
3. Economic analyses.
4. Communications before proposal consisting of written public and intra- or interagency memoranda and comments and summaries of telephone conversations.
5. Reports—published and unpublished factual materials.
6. Comments received in response to the proposed rule and the proposed amendment to the rule from the following organizations:

Ameribrom, Incorporated
Cambridge Isotope Laboratories, Inc.
Chemical Manufacturers Association, Inc.
Dow Chemical Company
Eastman Kodak Company
Ethyl Corporation
Environmental Defense Fund
Great Lakes Chemical Company
Imperial Chemicals, Inc.
Platte Chemical Company
Uniroyal Chemical, Inc.
Vulcan Chemicals, Inc.
Worker's Institute for Safety and Health
2,4-D Task Force

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 in the OPTS Reading Room, NE-G004, 401 M St., SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

XI. References

(1) Albro et al. "A Radioimmunoassay for Chlorinated Dibenzo-p-Dioxins." *Toxicology and Applied Pharmacology*. 50:137–146. 1979.

(2) Bandiera et al. "Polychlorinated dibenzofurans (PCDFs): Effects of structure on binding to the 2,3,7,8-TCDD cytosolic receptor protein, AHH induction and toxicity." *Toxicology*. 32:131–144. 1984.

(3) Bandiera et al. "Competitive binding to cytosolic 2,3,7,8-TCDD receptor: Effects of structure on the affinities of substituted halogenated biphenyls—a QSAR analysis." *Biochemical Pharmacology*. 32:3803. 1983.

(4) Bellin, J.S., Barnes D.G.; "Health Hazard Assessment for Chlorinated Dioxins and Dibenzofurans Other than 2,3,7,8-TCDD." Presented at the Symposium on advances in health risk assessment for systemic toxicants and chemical mixtures. Cincinnati, Ohio. October 25, 1984.

(5) Bomberger et al."Hexachlorobenzene: Chemistry of formation and identified sources." SRI draft report to USEPA. Office of Pesticides and Toxic Substances. Contract No. 68–02–3976. 1984.

(6) Bradlaw, J.A., Casterline J.L., Culture: A Rapid Screen for Detection of Planar Polychlorinated Organic Compounds." *Journal of Association of Official Analytical Chemistry*. 62:904–916. 1979.

(7) Crummet et al. Review and Trends in the Analysis for PCDD/PCDF. Dow Chemical Company Analytical Laboratories. 1986.

(8) Cull et al. "Polychlorodibenzo-P-Dioxins and Dibenzofurans in Technical Pentachlorophenol-Results of a Collaborative Analytical Exercise." *Chemosphere*, 13: 10:1157–1165. 1984.

(9) Czuczwa et al. "Polychlorinated Dibenzodioxins and Dibenzofurans in Sediments from Siskiwit Lake, Isle Royale." *Chemosphere*, 14: 6/7:623–626. 1985.

(10) Czuczwa, J.M., Hites, R. A. "Environmental Fate of Combustion-Generated Polychlorinated Dioxins and Furans." *Environmental Science and Technology*, 18:6:444–450. 1984.

(11) Dioxins '84: Report on Dioxins. Update to November 1984. Compiled by the Federal Health Office, Federal Environmental Agency, Federal Republic of Germany.

(12) Dow Chemical Company. Direct testimony of David T. Buzzelli before EPA in re: Docket No. 415 et al. Exhibit 810. Oct. 14, 1980.

(13) Dynamac Corporation, Environmental Control Division. Pre-Regulatory Analysis of Flame Retardants. EPA Contract No. 68–01–6239. May 7, 1982.

(14) Environmental Defense Fund and National Wildlife Federation. Petition to EPA to initiate rulemakings to prevent and reduce environmental contamination by dioxins and furans. October 22, 1984.

(15) Esposito et al. USEPA, "Dioxins," Cincinnati, Ohio. USEPA Industrial Environmental Research Laboratory, EPA 600/2–80–197. 1980.

(16) Gierthy et al. "Application of an *in vitro* Keratinization Assay to Extracts of Soot From a Fire in a PCB Containing Transformer." In press. *Fundamental and Applied Toxicology*. 1985.

(17) Helder T.H., Seinen W., "Standardization of an ELS Bioassay for PCDDs and PCDFs." *Chemosphere*, 14:183–193. 1983.

(18) Hoare et al. "Agricultural Herbicide Use and Risk of Lymphoma and Soft Tissue Sarcoma." *Journal of the American Medical Association*, 256: 9: 1141–1147. Sept. 1986.

(19) Hutzinger et al. "Polychlorinated Dibenzo-p-Dioxins and Dibenzofurans: A Bioanalytical Approach." *Chemosphere*, 10:19–25. 1981.

(20) Knutson, J.C., Poland A., "Keratinization of mouse teratome cell line XB produced by 2,3,7,8-tetrachlorodibenzo-p-dioxin: an *in vitro* model of toxicity." *Cell* 22:27–36. 1980.

(21) Mason et al. "Polychlorinated dibenzofurans (PCDFs) Correlation between *in vivo* and *in vitro* structure-activity relationships." *Toxicology*, 37:1. 1985.

(22) McKinney et al. "Structure Specificity and the Dioxin Receptor." In: Chlorinated Dioxins and Related Compounds: Impact on the Environment," by Hutzinger et al. Ed. Pergamon Press, p. 367. 1982.

(23) McKinney et al. "Development and Reliability of a Radioimmunoassay for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin." In: Impact of Chlorinated Dioxins and Related Compounds on the Environment. Hutzinger, eds. Oxford: Peragamon Press pp. 67–69. 1981.

(24) Midwest Research Institute (MRI). Guidelines for the Determination of Polyhalogenated Dioxins and Dibenzofura in Commercial Products. EPA contract No 68–02–3938; MRI Project No. 8201-A(41). 19

(25) Moore et al. "Comparative Toxicity of 3 Halogenated Dibenzofurans in Guinea Pigs, Mice, and Rhesus Monkeys." *N.Y. Academy of Science Annual*, 320, pp. 151–163. 1979.

(26) Patterson et al. "2,3,7,8-Tetrachlorodibenzo-p-Dioxin Levels in Adipose Tissue of Exposed and Control Persons in Missouri." *Journal of the American Medical Association*. Vol. 256. 19:2683–2686. November 21, 1986.

(27) Poland, A., Knutson J.C., "2,3,7,8-Tetrachlorodibenzo-p Dioxin and Related Halogenated Aromatic Hydrocarbons: Examination of the Mechanism of Toxicity." *Annual Review Pharmacology and Toxicology*. 22:517. 1982.

(28) Safe et al. Binding to the 2,3,7,8-TCDD Receptor and AHH/EROD Induction: *In vitro* QSAR. Banbury Report 18: Biological Mechanisms of Dioxin Action. Cold Spring Harbor Laboratory. 1984.

(29) Schwetz et al. "Toxicology of Chlorinated Dibenzo-p-Dioxins." *Environmental Health Perspectives*. 5:87–89. 1973.

(30) Thoma et al. "Polybrominated Dibenzodioxins and Furans from the Pyrolysis of Flame Retardants." *Chemosphere*, Vol. 15, No. 5, pp. 649–652. Pergamon Press. 1986.

(31) Thoma et al. "Polybrominated Dibenzofurans (PBDF) and Dibenzodioxins (PBDD) from the Pyrolysis of Neat Brominated Diphenylethers, Biphenyls a Plastic Mixtures of These Compounds." *Chemosphere* (In Press).

(32) USEPA OWRS, and OSWER. "Dioxin Strategy." Washington, D.C. Office of Water Regulations and Standards and Office of Solid Waste and Emergency Response in conjunction with the Dioxin Strategy Task Force. 1983.

(33) USEPA, OW. "Ambient Water Quality Criteria Document for 2,3,7,8-Tetrachlorodibenzo-p Dioxin." Washington, D.C. EPA 440/5–84–007. 1984.

(34) USEPA, ORD, OHEA, and ECAO. "Health Assessment Document for Polychlorinated Dibenzo-p Dioxins." September 1985.

(35) USEPA. Letter from Richard Griesemer, Chairman, Dioxin Toxic Equivalency Methodology Subcommittee, a Norton Nelson, Chairman, Executive Committee, to Lee M. Thomas, Administrat EPA. November 4, 1986. SAB–EC–87–008.

(36) USEPA OPTS and OTS. Personal Communication from Dr. Stephen Billet, EP to Dr. Peter Tong, OTS, HERD, CREB, re: Chemical Screening Methods for the Detection of PHDDs and PHDFs. June 3, 19

(37) USEPA, OPTS, OTS and ETD. Economic analysis of final section 8(a) reporting rule for chemicals potentially contaminated with polyhalogenated dibenz p-dioxins and polyhalogenated dibenzofurans. December, 1986.

(38) USEPA, OPTS, OTS and ETD. Economic anaysis of final Data Call-In TSCA section 8(c) of allegations of sig

adverse reactions for chemicals potentially contaminated with polyhalogenated dibenzo-p-dioxins and polyhalogenated dibenzofurans. December, 1986.

(39) USEPA, OPTS, OTS and ETD. Economic analysis for requirement under TSCA section (d) for submission of unpublished health and safety studies for chemicals potentially contaminated with polyhalogenated dibenzo-p-dioxins and polyhalogenated dibenzofurans. December, 1986.

(40) USEPA, OPTS. Report of The Dioxin Update Committee. Review of the Toxicology, Bioavailability, Pharmacokinetics, Mechanism of Action, and Human Risks Associated with Dioxins. August 1986.

(41) USEPA, OPTS, OTS and ETD. Economic analysis of final section 4 testing rule for chemicals potentially contaminated with polyhalogenated dibenzo-p-dioxins and polyhalogenated dibenzofurans. January, 1987.

(42) USEPA, OPTS, OTS. Memo from Denise M. Keehner, Chief, Chemical Regulation Branch, Exposure Evaluation Division, to the Rulemaking Record. May 4, 1987.

(43) Versar, Inc. List of chemicals contaminated or precursors to contamination with incidentally generated polychlorinated and polybrominated dibenzodioxins and dibenzofurans. EPA contract No. 68-02-3968, Task No. 48. 1985.

XII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the effect on the economy is not expected to exceed the advantages to the public of testing 12 chemicals and reporting on those contaminated, plus some additional reporting. The total costs of testing are expected to be $2.37 million. No significant increases in prices are expected to occur as a result of this rule, as reported in the economic impact analysis. No significant adverse effects are expected on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises.

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

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 et seq., Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) Very few small chemical manufacturers and importers will be required to test chemicals and report, and (2) small manufacturers have been exempted from a major reporting requirement.

For this rule, the definition of small business is the one codified at 40 CFR 704.3. For this certification, the total annual sales figure of $4 million, or $40 million and less than 100,000 pounds annual production was used as the cutoff to denote small chemical manufacturers and importers.

Of the firms likely to be required to test, four qualify as small businesses. These four firms do not represent a substantial number of all small chemical manufacturing firms. For each of these four firms, amortized test and reporting costs are projected to be less than 0.1 percent of annual sales, approximately the same percentage experienced by larger manufacturing and importing companies.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control numbers 2070-0033 for reporting under section 4, 2070-0004 for submission of health and safety studies under section 8(d), 2070-0017 for submission of allegations of significant adverse reactions under section 8(c), and 2070-0054 for submission of information under section 8(a).

List of Subjects in 40 CFR Parts 707 and 766

Chemicals, Environmental protection, Hazardous material, Health and safety, Recordkeeping and reporting requirements, Significant adverse reactions, Testing.

Dated: May 20, 1987.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter I is amended as follows:

PART 707—[AMENDED]

1. In Part 707:

a. The authority citation for Part 707 continues to read as follows:

Authority: 15 U.S.C. 2611(b) and 2612.

b. By adding a new § 707.72 to Subpart D to read as follows:

§ 707.72 Termination of reporting requirements.

(a) The reporting requirements of Subpart D of this Part are terminated for certain specific chemical substances and mixtures as set forth in this paragraph.

(1) When data required under Part 766 of this chapter have been submitted to EPA for a specific chemical substance produced by a specific process, and the data show no positive test result as defined in § 766.3 of this chapter, reporting is no longer required by persons who export or intend to export that substance produced by that process.

(2) [Reserved]

(b) [Reserved]

2. By adding Part 766 to read as follows:

PART 766—DIBENZO-PARA-DIOXINS/DIBENZOFURANS

Subpart A—General Provisions

Subpart B—Specific Chemical Testing/Reporting Requirements

Authority: 15 U.S.C. 2603 and 2607.

§ 766.1 Scope and purpose.

(a) This Part identifies requirements for testing under section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, to ascertain whether certain specified chemical substances may be contaminated with halogenated dibenzodioxins (HDDs)/dibenzofurans (HDFs) as defined in § 766.3, and requirements for reporting under section 8 of TSCA, 15 U.S.C. 2607.

(b) Section 766.35(b) requires manufacturers and processors of chemical substances identified in § 766.25 to submit to EPA: (1) Any existing test data showing analysis of the chemical substances for concentrations of HDDs/HDFs, applicable protocols, and the results of

the analysis for HDDs/HDFs, (2) allegations of significant adverse reactions to HDDs/HDFs, compiled in accordance with Part 717 of this chapter, and (3) health and safety studies on the HDDs/HDFs, in accordance with applicable provisions of Part 716 of this chapter.

(c) Section 766.35(a) requires manufacturers and, under certain circumstances, processors of chemical substances identified in § 766.25 to submit letters of intent to test and protocols for the analysis of the chemical substances for the presence of HDDs/HDFs. Section 766.20 requires these manufacturers and processors to test their chemical substances for the presence of HDDs/HDFs. Any submissions must be in accordance with the EPA Procedures Governing Testing Consent Agreements and Test Rules contained in Part 790 of this chapter and any modifications to such procedures contained in this Part.

(d) Section 766.32 specifies conditions under which persons required to test may request an exclusion or waiver from testing.

(e) Deadlines for submission to EPA of protocols, reports, studies, and test results are specified in Part 790 Subpart C and § 766.35.

(f) Sections 766.10, 766.12, 766.14, 766.16, and 766.18 prescribe analytical methods required; § 766.27 prescribes target levels of quantitation (LOQ) for each congener for which quantitation is required.

(g) If results of existing tests or tests performed under this Part indicate the presence of HDDs/HDFs in the identified chemical substance above the LOQ specified in § 766.27, § 766.35(c) requires the following additional reporting on the specified chemicals: production, process, use, exposure and disposal data under section 8(a) of TSCA; health and safety studies under section 8(d) of TSCA; and reports of allegations of significant adverse reactions under section 8(c) of TSCA. In some cases, additional reporting may be required of manufacturers reporting no contamination of the identified chemical substances under § 766.35(c)(2).

(h) Section 766.38 requires manufacturers of chemical substances produced from chemical substances identified as possible precursors to HDD/HDF formation, to report on chemical substances produced from such precursors.

§ 766.2 Applicability and duration of this part.

(a) *Chemical substances subject to testing.* (1) This Part is applicable to each person who, at any time during the duration of this Part, manufactures (and/or imports), or processes, a chemical substance identified under § 766.25.

(2) The duration of this Part for any testing requirement for any chemical substance is the period commencing with the effective date of this Part to the end of the reimbursement period, as defined in § 766.3, for each chemical substance. All reporting requirements for any chemical substance listed under § 766.25 shall be in effect for the same period as the testing requirement.

(b) *Precursor chemical substances.* (1) This Part is applicable to each person who manufactures (and/or imports) a chemical substance from any precursor chemical substance identified in § 766.38.

(2) The requirement for precursor reporting under § 766.38 shall be in effect until three years after the effective date of this Part.

(3) Small manufacturers are exempt from reporting process and reaction condition data on chemical substances made from precursor chemical substances listed under § 766.38.

§ 766.3 Definitions.

The definitions in section 3 of TSCA and the definitions of §§ 704.3, 716.3, 717.3, and 790.3 of this chapter also apply to this Part.

"Congener" means any one particular member of a class of chemical substances. A specific congener is denoted by unique chemical structure, for example 2,3,7,8-tetrachlorodibenzofuran.

"Dibenzofuran" means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of bridges between the benzene rings. The bridges are a carbon-carbon bridge and a carbon-oxygen-carbon bridge at both substitution positions.

"Dibenzo-p-dioxin" or "dioxin" means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of oxygen atoms.

"Guidelines" means the Midwest Research Institute (MRI) publication *Guidelines for the Determination of Polyhalogenated Dioxins and Dibenzofurans in Commercial Products*, EPA contract No. 68-02-3938; MRI Project No. 8201-A(41), 1985.

"HDD" or "2,3,7,8-HDD" means any of the dibenzo-p-dioxins totally chlorinated or totally brominated at the following positions on the molecular structure: 2,3,7,8; 1,2,3,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; and 1,2,3,4,6,7,8,9.

"HDF" or "2,3,7,8-HDF" means any of the dibenzofurans totally chlorinated or totally brominated at the following positions on the molecular structure: 2,3,7,8; 1,2,3,7,8; 2,3,4,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; 2,3,4,6,7,8; 1,2,3,4,6,7,8; and 1,2,3,4,7,8,9.

"Homolog" means a group of isomers that have the same degree of halogenation. For example, the homologous class of tetrachlorodibenzo-p-dioxins consists of all dibenzo-p-dioxins containing four chlorine atoms. When the homologous classes discussed in this Part are referred to, the following abbreviations for the prefix denoting the number of halogens are used:

tetra-, T (4 atoms)
penta-, Pe (5 atoms)
hexa-, Hx (6 atoms)
hepta-, Hp (7 atoms)

"HRGC" means high resolution gas chromatography.

"HRMS" means high resolution mass spectrometry.

"Level of quantitation" or "LOQ" means the lowest concentration at which HDDs/HDFs can be reproducibly measured in a specific chemical substance within specified confidence limits, as described in this Part.

"Polybrominated dibenzofurans" refers to any member of a class of dibenzofurans with two to eight brom substituents.

"Polybrominated dibenzo-p-dioxin" or "PBDD" means to any member of a class of dibenzo-p-dioxins with two to eight bromine substituents.

"Polychlorinated dibenzofuran" means any member of a class of dibenzofurans with two to eight chlorine substituents.

"Polychlorinated dibenzo-p-dioxin" or "PCDD" means any member of a class of dibenzo-p-dioxins with two to eight chlorine substituents.

"Polyhalogenated dibenzofuran" or "PHDF" means any member of a class o dibenzofurans containing two to eight chlorine, bromine, or a combination of chlorine and bromine substituents.

"Polyhalogenated dibenzo-p-dioxin" or "PHDD" means any member of a class of dibenzo-p-dioxins containing two to eight chlorine substituents or two to eight bromine substituents.

"Positive test result" means: (1) Any resolvable gas chromatographic peak fo any 2,3,7,8-HDD or HDF which exceeds the LOQ listed under § 766.27 for that congener, or (2) exceeds LOQs approve by EPA under § 766.28.

"Precursor" means a chemical substance which is not contaminated due to the process conditions under which it is manufactured, but becau its molecular structure, and under

favorable process conditions, it may cause or aid the formation of HDDs/HDFs in other chemicals in which it is used as a feedstock or intermediate.

"QA" means quality assurance.

"QC" means quality control.

"Reimbursement period" means the period that begins when the data from the last test to be completed under this Part for a specific chemical substance listed in § 766.25 is submitted to EPA, and ends after an amount of time equal to that which had been required to develop that data or 5 years, whichever is later.

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

§ 766.5 Compliance.

Any person who fails or refuses to comply with any aspect of this Part is in violation of section 15 of TSCA. Section 15(1) makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this Part. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17 of TSCA, the district courts of the United States have jurisdiction to restrain any violation of section 15.

§ 766.[illegible] Submission of information.

All information (including letters of intent, protocols, data, forms, studies, and allegations) submitted to EPA under this Part must bear the applicable Code of Federal Regulations (CFR) section number (e.g., § 766.20) and must be addressed to: Document Control Office (TS–790), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

§ 766.10 Test standards.

Testing required under Subpart B of this Part must be performed using the protocols submitted to and reviewed by the EPA expert panel established under § 766.28. All new data, documentation, records, protocols, specimens, and reports generated as a result of testing under Subpart B of this Part must be fully developed and retained in accordance with 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 EPA in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA Good Laboratory Practices (GLPs) published in Part 792 of this chapter. Sponsors must notify the laboratory that the testing is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the testing abide by the TSCA GLP standards. At the time test data are submitted, manufacturers must submit a certification to EPA that the laboratory performing the testing adhered to the TSCA GLPs.

§ 766.12 Testing guidelines.

Analytical test methods must be developed using methods equivalent to those described or reviewed in *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products.* Copies are available from the TSCA Assistance Office, (TS–799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 (800–424–9065). Copies are also located in the public docket for this Part (docket no. OPTS–83002) and are available for inspection in the OPTS Reading Rm., NE–G004, 401 M St., SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

§ 766.14 Contents of protocols.

Protocols should include all parts of the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins,* as stated in the Guidelines. For each chemical substance and each process, the manufacturer must submit a statement of how many grades of the chemical substance it produces, a justification for selection of the specific grade of chemical substance for testing, specific plans for collection of samples from the process stream, naming the point of collection, the method of collecting the sample, and an estimate of how well the samples will represent the material to be characterized; a description of how control samples (blanks) and HDD/HDF-reinforced control samples, or isotopically labeled compounds (standards) and duplicate samples will be handled; a description of the chemical extraction and clean up procedures to be used; how extraction efficiency and measurement efficiency will be established; and a description of instrument hardware and operating conditions, including type and source of columns, carrier gas and flow rate, operating temperature range, and ion source temperature.

§ 766.16 Developing the analytical test method.

Because of the matrix differences of the chemicals listed for testing, no one method for sample selection, preparation, extraction and clean up is prescribed. For analysis, High Resolution Gas Chromatography (HRGC) with High Resolution Mass Spectrometry (HRMS) is the method of choice, but other methods may be used if they can be demonstrated to reach the target LOQs as well as HRGC/HRMS.

(a) *Sample selection.* The chemical product to be tested should be sampled so that the specimens collected for analysis are representative of the whole. Additional guidance for sample selection is provided under § 766.12.

(b) *Sample preparation.* The sample must be mechanically homogenized and subsampled as necessary. Subsamples must be spiked or reinforced with surrogate compounds or with standard stock solutions, and the surrogates or standards must be thoroughly incorporated by mechanical agitation. Additional guidance is provided under § 766.12.

(c) *Sample extraction and cleanup.* The spiked samples must be treated to separate the HDDs/HDFs from the sample matrix. Methods are reviewed in the Guidelines under § 766.12, but the final method or methods are left to the discretion of the analyst, provided the instrumental response of the surrogates meets the criteria listed in the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins,* appendixes B and C of the Guidelines. Cleanup techniques are described in the Guidelines. These are chosen at the discretion of the analyst to meet the requirements of the chemical matrix.

(d) *Analysis.* The method of choice is High Resolution Gas Chromatographic/High Resolution Mass Spectrometric Determination, (HRGC/HRMS) but alternate methods may be used if the manufacturer can demonstrate that the method will reach the target LOQs as well as HRGC/HRMS. Specific operating requirements are found in the Guidelines.

§ 766.18 Method sensitivity.

The target level of quantitation required under § 766.27 for each HDD/HDF congener is the level which must be attempted for each resolved HRGC peak for that congener. For at least one product sample, at least two analyses of the same isotopically labeled HDD/HDF internal calibration standards spiked to a final product concentration equal to the LOQ for that congener must be

reproducibly extracted, cleaned up, and quantified to within ±20 percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 50 to 150 percent of the amount spiked, and the results must be corrected for recovery.

Subpart B—Specific Chemical Testing/ Reporting Requirements

§ 776.20 Who must test.

(a) Any person who manufactures, imports, or processes a chemical substance listed in § 766.25 must test that chemical substance and must submit appropriate information to EPA according to the schedules described in § 766.35. Chemical substances manufactured, imported or processed between January 1, 1984 and the date of promulgation of this Part are subject to testing upon the effective date of this Part. All other chemical substances are subject to testing immediately upon manufacture, import or processing. EPA expects that only manufacturers and importers will perform testing, and that the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the cost of testing. However, processors will be called upon to sponsor testing should manufacturers and importers fail to do so. A processor may apply for an exemption from testing upon certification to EPA that a manufacturer or importer is testing the chemical substance which that person processes.

(b) If no manufacturer or importer described in § 766.20 submits a letter of intent to perform testing within the period described under § 766.35(a), or an exemption application under § 790.45(a), or a request for an exclusion or waiver under § 766.32, EPA will issue a notice in the **Federal Register** to notify all processors of that chemical substance. The notice will state that EPA has not received any of the documents described in the previous sentence, and that current processors will have 30 days to submit either a letter of intent to perform the test or submit an exemption application.

(c) If no manufacturer, importer or processor submits a letter of intent to perform testing of a specific chemical substance produced by a specific process, EPA will notify all manufacturers, importers, and processors, either by notice in the **Federal Register** or by letter, that all exemption applications will be denied and that within 30 days all manufacturers, importers, and processors will be in violation of this Part until a proposed study plan is submitted for required testing.

(d) Manufacturers, importers, and processors who are subject to this Part must comply with the test rule development and exemption procedures in Part 790 of this chapter, except as modified in this Part.

§ 766.25 Chemical substances for testing.

(a) *Listing of chemical substances.* Chemical substances required to be tested for HDDs/HDFs under this rule are listed in this section. The listing is by Chemical Abstracts Service (CAS) Number and common name.

Note.—For purposes of guidance only, EPA lists the chemical substances subject to testing under this Part in two classes—those known to be manufactured or imported between January 1, 1984, and promulgation of this Part, and those not known to be manufactured or imported at the time of promulgation of this Part.

(1) *Chemicals substances known to be manufactured between January 1, 1984 and date of promulgation of this Part.*

CAS No.	Chemical name
79-94-7	Tetrabromobisphenol-A.
118-75-2	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione.
118-79-6	2,4,6-Tribromophenol.
120-83-2	2,4-Dichlorophenol.
1163-19-5	Decabromodiphenyloxide.
4162-45-2	Tetrabromobisphenol-A-bisethoxylate.
21850-44-2	Tetrabromobisphenol-A-bis-2,3-dibromopropyl ether.
25327-89-3	Allyl ether of tetrabromobisphenol-A.
32534-81-9	Pentabromodiphenyloxide.
32536-52-0	Octabromodiphenyloxide.
37853-59-1	1,2-Bis(tribromophenoxy)-ethane.
55205-38-4	Tetrabromobisphenol-A diacrylate.

(2) *Chemicals not known to be manufactured between January 1, 1984 and the date of promulgation of this Part.*

CAS No.	Chemical name
79-95-8	Tetrachlorobisphenol-A.
87-10-5	3,4',5-Tribromosalicylanilide.
87-65-0	2,6-Dichlorophenol.
95-77-2	3,4-Dichlorophenol.
95-95-4	2,4,5-Trichlorophenol.
99-28-5	2,6-Dibromo-4-nitrophenol.
120-36-5	2[2,4-(Dichlorophenoxy)]-propionic acid.
320-72-9	3,5-Dichlorosalicyclic acid.
488-47-1	Tetrabromocatechol.
576-24-9	2,3-Dichlorophenol.
583-78-8	2,5-Dichlorophenol.
608-71-9	Pentabromophenol.
615-58-7	2,4-Dibromophenol.
933-75-5	2,3,6-Trichlorophenol.
1940-42-7	4-Bromo-2,5-dichlorophenol.
2577-72-2	3,5-Dibromosalicylanilide.
3772-94-9	Pentachlorophenyl laurate.
37853-61-5	Bismethylether of tetrabromobisphenol-A.
	Alkylamine tetrachlorophenate.
	Tetrabromobisphenol-B.

(b) *Grade to be tested.* If the same process is used to manufacture all grades of the same chemical substance, only one grade need be tested. The grade to be tested must be the gra[de] subject to the most intense heat a[nd] alkalinity for the longest duration of time, manufactured under each differen[t] process. If the heat, alkalinity and duration of reaction do not differ for various grades, the test substance must be the grade of chemical substance wit[h] the highest volume of sales.

§ 766.27 Congeners and LOQs for which quantitation is required.

Quantitation at the target LOQ shown for each of the following HDDs/HDFs which may be present in the chemical substances is required for the chemical substances listed under § 766.25. Analysis must take place for either chlorinated or brominated dibenzodioxins or dibenzofurans, whichever is predominantly expected t[o] occur in the chemical substance to be tested. Only chlorinated and brominate congeners need be quantified; for chemical substances containing predominantly chlorine atoms, only congeners totally chlorinated at the numbered positions need be quantified; for chemical substances containing predominantly bromine atoms, only congeners totally brominated at the numbered positions need be quanti[fied].

Chlorinated dioxins	Brominated dioxins	
2,3,7,8-TCDD	2,3,7,8-TBDD	0.1 ppb.
1,2,3,7,8-PeCDD	1,2,3,7,8-PeBDD	0.5 ppb.
1,2,3,4,7,8-HxCDD	1,2,3,4,7,8-HxBDD	2.5 ppb.
1,2,3,6,7,8-HxCDD	1,2,3,6,7,8-HxBDD	2.5 ppb.
1,2,3,7,8,9-HxCDD	1,2,3,7,8,9-HxBDD	2.5 ppb.
1,2,3,4,6,7,8-HpCDD	1,2,3,4,6,7,8-HpBDD	100 ppb.
2,3,7,8-TCDF	2,3,7,8-TBDF	1 ppb.
1,2,3,7,8-PeCDF	1,2,3,7,8-PeBDF	5 ppb.
2,3,4,7,8-PeCDF	2,3,4,7,8-PeBDF	5 ppb.
1,2,3,4,7,8-HxCDF	1,2,3,4,7,8-HxBDF	25 ppb.
1,2,3,6,7,8-HxCDF	1,2,3,6,7,8-HxBDF	25 ppb.
1,2,3,7,8,9-HxCDF	1,2,3,7,8,9-HxBDF	25 ppb.
2,3,4,6,7,8-HxCDF	2,3,4,6,7,8-HxBDF	25 ppb.
1,2,3,4,6,7,8-HpCDF	1,2,3,4,6,7,8-HpBDF	1 ppm.
1,2,3,4,7,8,9-HpCDF	1,2,3,4,7,8,9-HpBDF	1 ppm.

§ 766.28 Expert review of protocols.

EPA will gather a panel of experts in analysis of chemical matrices for HDD. HDFs to review the protocols for testin submitted to EPA. The panel members will be employees of EPA and/or of other U.S. Government agencies who have had experience in analysis of chemical matrices and/or chemical wastes for HDDs/HDFs. The panel wil[l] recommend to the Director, EPA Office of Toxic Substances, whether the protocol submitted is likely to allow analysis down to the target LOQs, or if not, whether the protocol represents a good faith effort on the part of the te[st] to achieve the lowest possible LO[Q]. The final determination to accept

reproducibly extracted, cleaned up, and quantified to within ±20 percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 50 to 150 percent of the amount spiked, and the results must be corrected for recovery.

Subpart B—Specific Chemical Testing/Reporting Requirements

§ 776.20 Who must test.

(a) Any person who manufactures, imports, or processes a chemical substance listed in § 766.25 must test that chemical substance and must submit appropriate information to EPA according to the schedules described in § 766.35. Chemical substances manufactured, imported or processed between January 1, 1984 and the date of promulgation of this Part are subject to testing upon the effective date of this Part. All other chemical substances are subject to testing immediately upon manufacture, import or processing. EPA expects that only manufacturers and importers will perform testing, and that the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the cost of testing. However, processors will be called upon to sponsor testing should manufacturers and importers fail to do so. A processor may apply for an exemption from testing upon certification to EPA that a manufacturer or importer is testing the chemical substance which that person processes.

(b) If no manufacturer or importer described in § 766.20 submits a letter of intent to perform testing within the period described under § 766.35(a), or an exemption application under § 790.45(a), or a request for an exclusion or waiver under § 766.32, EPA will issue a notice in the **Federal Register** to notify all processors of that chemical substance. The notice will state that EPA has not received any of the documents described in the previous sentence, and that current processors will have 30 days to submit either a letter of intent to perform the test or submit an exemption application.

(c) If no manufacturer, importer or processor submits a letter of intent to perform testing of a specific chemical substance produced by a specific process, EPA will notify all manufacturers, importers, and processors, either by notice in the **Federal Register** or by letter, that all exemption applications will be denied and that within 30 days all manufacturers, importers, and processors will be in violation of this Part until a proposed study plan is submitted for required testing.

(d) Manufacturers, importers, and processors who are subject to this Part must comply with the test rule development and exemption procedures in Part 790 of this chapter, except as modified in this Part.

§ 766.25 Chemical substances for testing.

(a) *Listing of chemical substances.* Chemical substances required to be tested for HDDs/HDFs under this rule are listed in this section. The listing is by Chemical Abstracts Service (CAS) Number and common name.

Note.—For purposes of guidance only, EPA lists the chemical substances subject to testing under this Part in two classes—those known to be manufactured or imported between January 1, 1984, and promulgation of this Part, and those not known to be manufactured or imported at the time of promulgation of this Part.

(1) *Chemicals substances known to be manufactured between January 1, 1984 and date of promulgation of this Part.*

CAS No.	Chemical name
79-94-7	Tetrabromobisphenol-A.
118-75-2	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione.
118-79-6	2,4,6-Tribromophenol.
120-83-2	2,4-Dichlorophenol.
1163-19-5	Decabromodiphenyloxide.
4162-45-2	Tetrabromobisphenol-A-bisethoxylate.
21850-44-2	Tetrabromobisphenol-A-bis-2,3-dibromopropyl ether.
25327-89-3	Allyl ether of tetrabromobisphenol-A.
32534-81-9	Pentabromodiphenyloxide.
32536-52-0	Octabromodiphenyloxide.
37853-59-1	1,2-Bis(tribromophenoxy)-ethane.
55205-38-4	Tetrabromobisphenol-A diacrylate.

(2) *Chemicals not known to be manufactured between January 1, 1984 and the date of promulgation of this Part.*

CAS No.	Chemical name
79-95-8	Tetrachlorobisphenol-A.
87-10-5	3,4',5-Tribromosalicylanilide.
87-65-0	2,6-Dichlorophenol.
95-77-2	3,4-Dichlorophenol.
95-95-4	2,4,5-Trichlorophenol.
99-28-5	2,6-Dibromo-4-nitrophenol.
120-36-5	2[2,4-(Dichlorophenoxy)]-propionic acid.
320-72-9	3,5-Dichlorosalicyclic acid.
488-47-1	Tetrabromocatechol.
576-24-9	2,3-Dichlorophenol.
583-78-8	2,5-Dichlorophenol.
608-71-9	Pentabromophenol.
615-58-7	2,4-Dibromophenol.
933-75-5	2,3,6-Trichlorophenol.
1940-42-7	4-Bromo-2,5-dichlorophenol.
2577-72-2	3,5-Dibromosalicylanilide.
3772-94-9	Pentachlorophenyl laurate.
37853-61-5	Bismethylether of tetrabromobisphenol-A.
	Alkylamine tetrachlorophenate.
	Tetrabromobisphenol-B.

(b) *Grade to be tested.* If the same process is used to manufacture all grades of the same chemical substance, only one grade need be tested. The grade to be tested must be the grade subject to the most intense heat and alkalinity for the longest duration of time, manufactured under each different process. If the heat, alkalinity and duration of reaction do not differ for various grades, the test substance must be the grade of chemical substance with the highest volume of sales.

§ 766.27 Congeners and LOQs for which quantitation is required.

Quantitation at the target LOQ shown for each of the following HDDs/HDFs which may be present in the chemical substances is required for the chemical substances listed under § 766.25. Analysis must take place for either chlorinated or brominated dibenzodioxins or dibenzofurans, whichever is predominantly expected to occur in the chemical substance to be tested. Only chlorinated and brominated congeners need be quantified; for chemical substances containing predominantly chlorine atoms, only congeners totally chlorinated at the numbered positions need be quantified; for chemical substances containing predominantly bromine atoms, only congeners totally brominated at the numbered positions need be quantified.

Chlorinated dioxins	Brominated dioxins	LOQ
2,3,7,8-TCDD	2,3,7,8-TBDD	0.1 ppb.
1,2,3,7,8-PeCDD	1,2,3,7,8-PeBDD	0.5 ppb.
1,2,3,4,7,8-HxCDD	1,2,3,4,7,8-HxBDD	2.5 ppb.
1,2,3,6,7,8-HxCDD	1,2,3,6,7,8-HxBDD	2.5 ppb.
1,2,3,7,8,9-HxCDD	1,2,3,7,8,9-HxBDD	2.5 ppb.
1,2,3,4,6,7,8-HpCDD	1,2,3,4,6,7,8-HpBDD	100 ppb.
2,3,7,8-TCDF	2,3,7,8-TBDF	1 ppb.
1,2,3,7,8-PeCDF	1,2,3,7,8-PeBDF	5 ppb.
2,3,4,7,8-PeCDF	2,3,4,7,8-PeBDF	5 ppb.
1,2,3,4,7,8-HxCDF	1,2,3,4,7,8-HxBDF	25 ppb.
1,2,3,6,7,8-HxCDF	1,2,3,6,7,8-HxBDF	25 ppb.
1,2,3,7,8,9-HxCDF	1,2,3,7,8,9-HxBDF	25 ppb.
2,3,4,6,7,8-HxCDF	2,3,4,6,7,8-HxBDF	25 ppb.
1,2,3,4,6,7,8-HpCDF	1,2,3,4,6,7,8-HpBDF	1 ppm.
1,2,3,4,7,8,9-HpCDF	1,2,3,4,7,8,9-HpBDF	1 ppm.

§ 766.28 Expert review of protocols.

EPA will gather a panel of experts in analysis of chemical matrices for HDDs/HDFs to review the protocols for testing submitted to EPA. The panel members will be employees of EPA and/or of other U.S. Government agencies who have had experience in analysis of chemical matrices and/or chemical wastes for HDDs/HDFs. The panel will recommend to the Director, EPA Office of Toxic Substances, whether the protocol submitted is likely to allow analysis down to the target LOQs, or if not, whether the protocol represents a good faith effort on the part of the tester to achieve the lowest possible LOQs. The final determination to accept or

reject the protocol will be made by the Director, Office of Toxic Substances. EPA will review the submitted protocols as rapidly as possible and will complete the review within 90 days after receipt. EPA may require submission of revised protocols. Comments and recommendations will be transmitted to the submitter, and if revisions are required, a final protocol must be submitted to EPA within 90 days after EPA transmits such recommendations.

§ 766.32 Exclusions and waivers.

(a) *Reasons for exclusions and waivers.* Any person subject to the testing requirements of this Part may request an exclusion or waiver from testing for any one of the following reasons:

(1) *Exclusions may be granted if.* (i) Testing of the appropriate grade of the chemical substance has already been carried out, either analytical testing at the lowest LOQ possible, with appropriate QA/QC, or a well-designed bioassay with appropriate QA/QC or;

(ii) Process and reaction conditions of the chemical substance such that no HDDs/HDFs could be produced under those conditions;

(2) *Waivers may be granted if.* (i) A responsible company official certifies that the chemical substance is produced only in quantities of 100 kilograms or less per year, only for research and development purposes; or

(ii) In the judgement of EPA, the cost of testing would drive the chemical substance off the market, or prevent resumption of manufacture or import of the chemical substance, if it is not currently manufactured, and the chemical substance will be produced so that no unreasonable risk will occur due to its manufacture, import, processing, distribution, use, or disposal. (In this case, the manufacturer must submit to EPA all data supporting the determination.)

(iii) Waivers may be appropriately conditioned with respect to such factors as time and conditions of manufacture or use. The grade of decabromodiphenyl oxide produced by Dow Chemical Company (Dow) for the National Toxicology Program (NTP) bioassay on that chemical is excluded from the testing requirement under this Part. Provided, however, that this exclusion will not apply if Dow fails to supply to EPA within 60 days of the effective date of this section evidence showing which grade was used for the NTP bioassay.

(b) *Timing.* Exclusion or waiver requests and detailed supporting data must be submitted to EPA within 60 days from the effective date of this Part for persons manufacturing, importing or processing a chemical substance as of the date of promulgation, or 60 days prior to the date of resumption of manufacture or import for a chemical substance produced by a specific process if the chemical substance is not manufactured, imported or processed as of the date of promulgation.

(c) *Publication.* Within 10 days of receipt of any exclusion or waiver request, EPA will issue in the Federal Register a notice of such receipt. EPA will also issue a notice of its decision on each exclusion or waiver request within 60 days of receipt.

(d) *Decision.* The EPA Director of the Office of Toxic Substances will make the decision to grant or deny waivers or exclusions.

§ 766.35 Reporting requirements.

(a) *Letters of intent, exemption applications, and protocols*—(1) *Letters of Intent.* (i) Persons who have manufactured or imported chemical substances listed under § 766.25 between January 1, 1984, and the effective date of this Part are required to submit under § 790.45 of this chapter a letter of intent to test or an exemption application. These letters must be submitted no later than September 3, 1987.

(ii) Persons who commence manufacture, import or processing of a chemical substance listed under § 766.25 that has not been manufactured, imported or processed between January 1, 1984 and the effective date of this Part must submit under § 790.45 of this chapter, within 60 days after the commencement of manufacture, import, or processing of the chemical substance, a letter of intent to test or an exemption application.

(iii) Persons who commence manufacture, import or processing of a chemical substance listed under § 766.25 between the effective date of this Part and the end of the reimbursement period for that particular chemical substance produced by a specific process must submit under § 790.45 of this chapter, within 60 days after the commencement of manufacture, import or processing of the chemical substance, a letter of intent to test or an exemption application.

(2) *Protocols.* (i) Each person who is manufacturing or processing a chemical substance listed in § 766.25 as of the effective date of this Part who submits a notice of intent to test under § 766.35(a)(1) must submit a protocol for the test as follows:

(A) The protocols for each chlorinated chemical substance produced by each process to be tested must be submitted to EPA no later than 12 months after the effective date of this Part.

(B) The protocol for each brominated chemical substance produced by each process to be tested must be submitted to EPA no later than 24 months after the effective date of this Part.

(ii) For chemical substances produced by a specific process not manufactured or processed as of the effective date of this Part, a person who begins manufacture and submits a notice of intent to test must submit protocols for the test as follows:

(A) Protocols for testing must be submitted 12 months after manufacture begins for chlorinated chemical substances.

(B) Protocols for testing must be submitted 24 months after manufacture begins for brominated chemical substances.

(iii) For persons who have been granted exemptions, waivers or exclusions from testing, protocols must be submitted 12 months after expiration of the exemption, waiver or exclusion for chlorinated chemical substances, and 24 months after expiration of the exemption, waiver or exclusion for brominated chemical substances.

(b) *Information that must be submitted to EPA.* (1) Persons who manufacture or import a chemical substance listed under § 766.25 must report no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, whichever is later, the results of all existing test data which show that chemical substance has been tested for the presence of HDDs/HDFs.

(2) Any manufacturer or importer of a chemical substance listed in § 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, whichever is later. The following provisions of Part 716 of this chapter apply to submission of these studies: §§ 716.3, 716.10(a) (1) and (4); 716.20(a) (1), (2), (3), (4), (7), (8) and (10); 716.25; 716.30; 716.35(a) (1), (2), and (4) [if applicable]; 716.35 (b) and (c); 716.40 (a) and (b); 716.50; 716.55; and 716.60(a)(2).

(3) No later than October 5, 1987 or 90 days after the person first manufactures or imports the substance listed in § 766.25, any manufacturer or importer of a chemical substance listed in § 766.25 must submit records required to be held under Part 717 of this chapter on any HDDs/HDFs.

(4) Test results. (i) Test results must be reported to EPA not later than 270 days after EPA's transmission of comments or 180 days after a final

protocol is submitted to EPA, whichever is shorter.

(ii) For purposes of reporting test results to EPA, and for further reporting triggered by a positive test result under § 766.35(c), a positive test result is defined at § 766.3.

(iii) Reporting of test results must follow procedures set out in Part 790 of this chapter, except as modified in this Part.

(c) *Information required to be submitted to EPA after submission of a positive test result.* (1) Any person who submits a positive test result for a specific chemical substance listed under § 766.25 must submit to EPA no later than 90 days after the date of submission of the positive test result the following:

(i) A completed form (EPA 7910–51) for that chemical substance. The form appears at paragraph (d)(5) of this section and copies are available from the TSCA Assistance Office, (TS–799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC, 80460. One form must be submitted for each chemical substance for which a positive test result has been submitted.

(ii) Health and safety studies for the chemical substance for which a positive test result has been reported. The following provisions of Part 716 of this chapter apply to submission of these studies: §§ 716.3; 716.10 (a) (1), (2), (3) and (4); 716.20; 716.25; 716.30; 716.35(a) (1), (2), and (4), [if applicable]; 716.35 (b) and (c); 716.40 (a) and (b); 716.50; 716.55; 716.60(a)(2).

(iii) Copies of records on the chemical substances required to be held under Part 717 of this chapter.

(2) If a positive test result on a chemical substance is received from a person but not from others, EPA may issue a notice in the **Federal Register** listing that chemical substance and requiring any person manufacturing, importing or processing that chemical substance who has not submitted a positive test result to submit the information required in Part II of EPA Form 7910–51 (appearing in § 766.35). Such a notice will be published only if EPA needs additional process data to make a determination of unreasonable risk.

(d) Dioxin/Furan Reporting Form

BILLING CODE 6560-50-M

United States Environmental Protection Agency
Washington, DC 20460

EPA

Dioxins/Furans Report

Form Approved
OMB No. 2070-0017
Approval expires 8/89

When completed, send this form to:

Document Control Officer
Office of Toxic Substances, TS-793
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

For Agency Use Only

Document Control Number	Docket Number

Part I — General Information

Section A — Submitter Identification

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

Confidential

1a. Person Submitting Notice

Name of authorized official | Title

Company

Mailing address *(number and street)*

City, State, and ZIP Code

Section B — Chemical Identity Information *(Use a separate form for each chemical reported.)*

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

1. Chemical name and CAS Registry Number

Part II — Process and Release Information

Section A — Flow Diagram

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

Complete this section for each unit process. Provide a general process block flow diagram that identifies major unit operations and treatment processes and indicate the types and points of release of byproducts and residuals. *(See example I attached.)*

(1) Include intermediates, coproducts and byproducts produced by the process.

(2) Proide a block for each major unit operation *(e.g., reactor, washer, filtration, air emission control, aeration lagoon, etc.)* in the production process and in the residuals management process.

(3) Identify process input such as raw materials, reagents, and solvents by chemical or common name and CAS number, and indicate the point of introduction with arrows.

(4) For each unit operation in which the temperature is not ambient, specify temperature or temperature range in each block of the flow diagram.

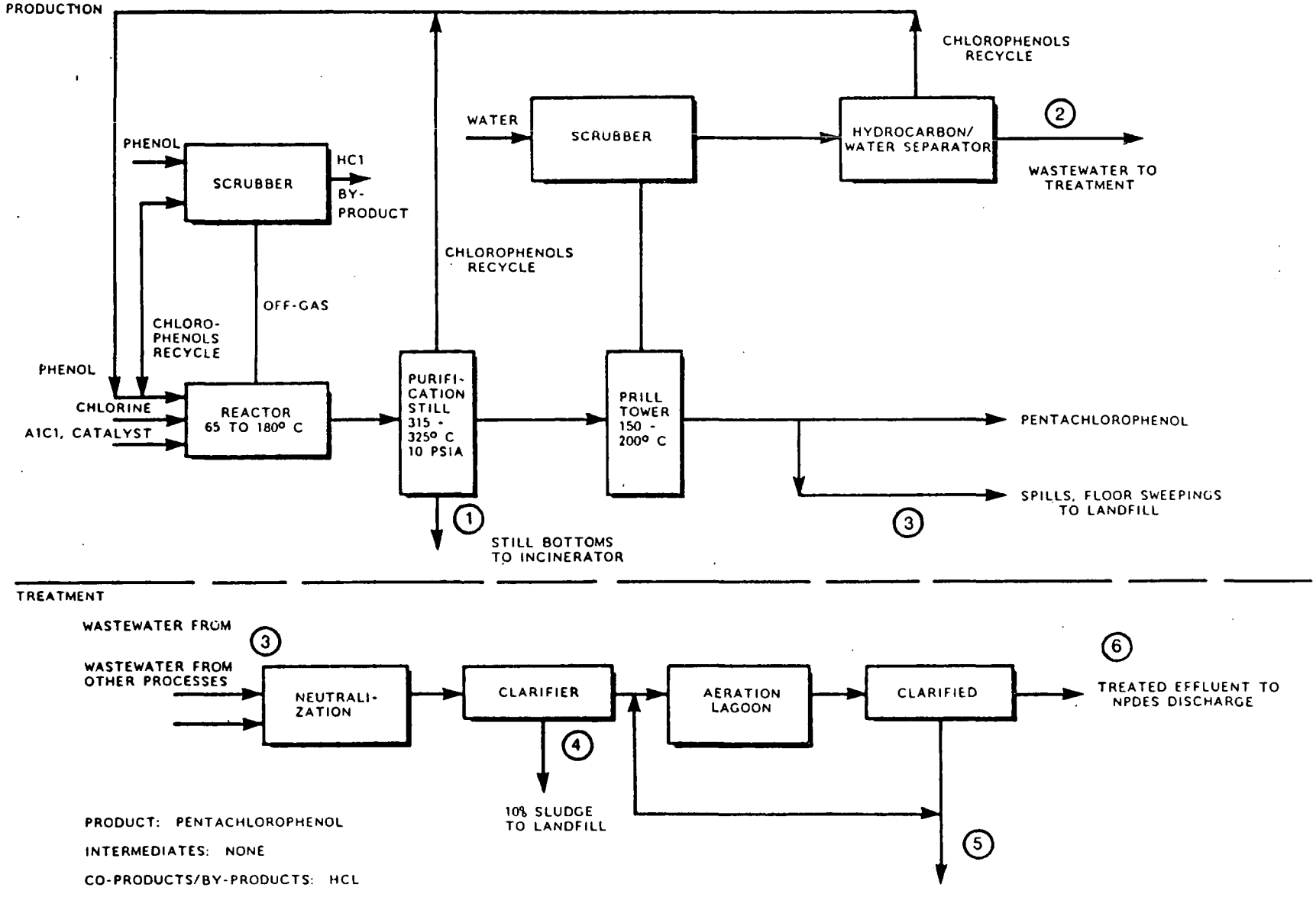
(5) Specify operating pressure or pressure range in each block of the flow diagram for each unit operation in which the pressure is not atmospheric.

(6) Identify the composition of the reaction vessel wherever one is used *(e.g., stainless steel, glass-lined)*.

(7) Number all points in the flow diagram from which the chemical substance will be released into the environment. *(See example I)*

☐ Mark (x) this box if you attach a continuation sheet

EXAMPLE I - PROCESS BLOCK FLOW DIAGRAM



Section B — Environmental Release and Disposal

You must make separate confidentiality claims for the release number and the amount of the substance released and other release and disposal information. Mark (x) the "Confidential" box next to each item you claim as confidential.

(1) — Enter the number of each release point identified in the process description, part II, Section A.
(2) — Estimate the amount of the chemical substance released directly to the environment or into control technology *(in kg/day or kg/batch)*.
(3) — Mark (x) this column if entries in columns (1) and/or (2) are confidential
(4) — Identify the media *(air, land, or water)* to which the substance will be released from the release point
(5) — Describe control technology, if any, that will be used to limit the release of the substance to the environment. For releases disposed of on land, characterize the disposal method.
(6) — Mark (x) this column if entries in columns (4) and/or (5) are confidential
(7) — Identify the destination(s) of releases to water.

Release Number *(1)*	Amount of substance released *(2)*	Confidential *(3)*	Media of release *(4)*	Control technology *(5)*	Confidential *(6)*

(7) Mark (x) the destination(s) of releases to water ☐ POTW *(publicly owned treatment works)* ☐ Navigable waterway ☐ Other *(specify)* ☐ Mark (x) this box if you attach a continuation sheet

EPA Form 7710-51 (9-85)

Part III — Production, Import, and Use Information

Mark (x) the "Confidential" box next to any item you claim as confidential.

1. **Production volume** — Report the production volume during the past 12 months of production. Also report the **maximum** production volume for any consecutive 12-month period during the past 3 years of production.

Past 12-month production *(kg/year)*	Maximum 12-month production *(kg/year)*	Confi-dential

2. **Use Information** — You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the substance, and other use information. Mark (x) the "Confidential" box next to any item you claim as confidential.

(1) — Describe each category of use of the chemical substance by function and application.
(2) — Mark (x) this column if entry in column (1) is confidential.
(3) — Estimate the percent of total production for the past 3 years devoted to each category of use.
(4) — Mark (x) this column if entry in column (3) is confidential.
(5) — Estimate the percent of the substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(6) — Mark (x) this column if entry in column (5) is confidential.
(7) — Mark (x) whether the use is site-limited, industrial, commercial, or consumer. Mark more than one column if appropriate.
(8) — Mark (x) this column if entries in column (7) are confidential.

Read the **Instructions Manual** for examples.

Category of use *(1)*	Confi-dential *(2)*	Production *(percent)* *(3)*	Confi-dential *(4)*	Formulation *(percent)* *(5)*	Confi-dential *(6)*	*Mark (x) appropriate column(s) (7)*				Confi-dential *(8)*
						Site-limited	Indus-trial	Com-mercial	Con-sumer	

☐ Mark (x) this box if you attach a continuation sheet.

3. **Hazard Information** — Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new chemical substance. List in part IV any hazard information you include.

☐ Mark (x) this box if you attach hazard information

4. **Occupational Exposure** — You must make separate confidentiality claims for the description of worker activity, physical form of the substances, number of workers exposed, and duration of activity. Mark (x) the "Confidential" box next to any item you claim as confidential.

(1) — Describe the activities in which workers may be exposed to the chemical substance. Include activities in which workers wear protective equipment
(2) — Mark (x) this column if entry in column (1) is confidential
(3) — Indicate the physical form(s) of the chemical substance at the time of exposure.
(4) — Mark (x) this column if entry in column (3) is confidential
(5) — Estimate the maximum number of workers involved in each activity
(6) — Mark (x) this column if entry in column (5) is confidential
(7) and (8) — Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(9) — Mark (x) this column if entries in column (7) and/or (8) are confidential

Worker Activity (1)	Confidential (2)	Physical Forms (3)	Confidential (4)	Maximum number (5)	Confidential (6)	Maximum duration		Confidential (9)
						Hrs/day (7)	Days/yr (8)	

☐ Mark (x) this box if you attach a continuation sheet.

EPA Form 7710-51 (9-86)

Part IV — List of Attachments

Attach continuation sheets for sections of the form and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In column (2) below, enter the inclusive page numbers of each attachment.

Mark (x) the "Confidential" box next to any attachment name you claim as confidential. Read the **Instructions Manual** for guidance on how to claim any information in an attachment as confidential.

Attachment name *(1)*	Attachment page numbers *(2)*	Confidential *(3)*

☐ Mark (x) this box if you attach a continuation sheet. Enter the attachment name and number.

Certification

I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1a of this form manufactures, imports, or proceses, other than in small quantities for research purposes, the substance identified in part I, section B.
2. All information provided in this notice is complete and truthful as of the date of submission.

Signature of authorized official	Date	Confidential

Signature of agent *(if applicable)*	Date	Confidential

EPA Form 7710-51 (9-86)

General Instructions
EPA Form 7710-51, Dioxins/Furans Report

You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you.

Part I — General Information

You must provide the chemical identity of the chemical substance reported on, even if you claim the identity as confidential.

Part II — Process and Release Information

You may need additional copies of part II, sections A and B if there are several manufacture operations that you will describe in the form. You should reproduce these sections as needed.

Part III — Production, Import, and Use Information

You must provide production volume, percent of production used for each use category, and whether use is industrial, commercial or consumer. Also included is a copy of any hazard warning and a report of occupational exposure. Copies may be made of any part of the form if additional space is needed.

Part IV — List of Attachments

You should attach additional sheets if you do not have enough space on the form to answer a question fully. In part IV, list all attachments you include with the form.

Optional Information

You may include with the form any information that you want EPA to consider in evaluating the substance.

Confidentiality Claims

You may claim any information in this form as confidential. To assert a claim on the form, mark (x) the "Confidential" box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential.

A. General Instructions

Complete the form using a typewriter or by printing legibly in black ink. All information must be in English. Provide all information requested on the form to the extent that you know or can reasonably ascertain it. You may attach continuation sheets to any subsection or item on the form. Mark (x) the appropriate box on the form if you attach continuation sheets.

The use of the term "manufacture" in this form includes both manufacture and import. Manufacturers and importers must fully comply with the information requirements set forth in the Polyhalogenated Dibenzo-p-dioxins/Dibenzofurans Testing and Reporting Requirements Rule. However, importers are not required to submit any data under section 8(a) of TSCA which relates solely to exposure to humans or the environment outside the United States.

Any manufacturer or importer using this form may photocopy the form, sections of the form, or these instructions as frequently as needed.

B. Certification

The official named in Part I, section A of the form, as the person submitting the notice, must sign the certification on page 6 of the form. This official is responsible for the truth and accuracy of each statement in the certification.

C. Asserting Confidentiality Claims

A manufacturer or importer may assert a claim of confidentiality for any information submitted to EPA on this form. To assert confidentiality claims for specific information on the form (e.g., submitter identity, process data, or use information), mark (x) in the "Confidential" box on the form located to the right of the information. Marking these boxes will provide a quick reference for EPA to determine what information is confidential, thus aiding proper treatment of confidential business information.

Part I — General Information

Section A — Submitter Identification

Person submitting notice — Enter information on the official who signed the general certification on page 6.

Section B — Chemical Identity Information

Chemical Name and CAS Registry Number — List the common name and Chemical Abstracts Registry number, if available, for the chemical on which you are reporting.

II. Process and Release Information

Section A — Flow Diagram

Flow diagram — Submit a block flow diagram for each major unit operation and treatment process involved in manufacturing the chemical on which you are reporting. Include the following information:

(1) identify the product process, and chemical intermediates, coproducts and byproducts produced by the process;

(2) provide a block for each major unit operation (e.g., reactor, washer, filtration, air emission control, aeration lagoon, etc.) in the production process and in the residuals management process;

(3) identify all process input such as raw materials, reagents, solvents, etc. by chemical or common name and CAS number, and indicate the point of introduction with arrows;

(4) for each unit operation in which the temperature is not ambient, specify temperature or temperature range in each block of the flow diagram;

(5) specify operating pressure or pressure range in each block of the flow diagram for each unit operation in which pressure is not atmospheric;

(6) identify the composition of the reaction vessel wherever one is used;

(7) number all points in the flow diagram from which the chemical substance will be released into the environment. See the example provided.

Section B — Environmental Release and Disposal

Column (1) — For each release point indicated in the flow diagram (part II, section A), enter the corresponding number.

Column (2) — Estimate the amount of the chemical (in kg/day for continuous operations or kg/batch for batch operations) that will be released from the release point before entering control technology. Base your estimate on your maximum 12-month production volume.

Column (4) — Enter the medium (air, water, land) into which the release stream discharges (whether or not control technology is used).

Column (5) — For releases to the air and water, describe the type of technology used to control the release of the chemical. Examples of control technologies include carbon filter, scrubber, and biological treatment (primary, secondary, etc.). Give as complete a description as possible. Enter "none" if no control technology is used and the substance is released directly to the environment. For disposal on land, describe the landfill site construction (including liners) and handling procedures. Describe landfill containers.

Column (7) — Mark (x) the appropriate box and/or specify other destinations of water releases.

Columns (3) and (6) — Note that you must make separate confidentiality claims for the release number and amount of chemical substance released and other release and disposal information.

Part III — Production, Import, and Use Information

A. Production Information

Production volume — Report the production volume for the past 12 months of production. Also report the maximum production volume for any consecutive 12-month period during the past 3 years of manufacture. Provide this information in kilograms. Include in your report the amounts produced by persons under contract to you. If part of the amount manufactured is for export, include this amount in your reports.

B. Use Information

Column (1) — Identify each possible category of use of the chemical substance by describing its function and application. "Function" is related to the inherent physical and chemical properties of the substance (e.g., degreaser, catalyst, plasticizer, ultraviolet absorber). "Application" refers to the use of the substance in particular processes or products (e.g., a degreaser may be used for cleaning of fabricated metal parts). Following are some examples of how you should describe categories of use:

- a disperse dye carrier for finishing polyester fibers
- a cross-linking agent for epoxy-like coatings for metal surfaces
- a flame retardant for surface application on cotton apparel, textile home furnishings, and exterior canvas products
- a surfactant in automobile spray wax
- a colorant for paper and other cellulosics

Column (3) — Report the percent of the total production volume during the past 12 months manufactured for each category of use.

Column (5) — Estimate the weight percent of the chemical substance contained in any formulated mixture, suspension, emulsion, solution, or gel associated with each category of use as manufactured for commercial purposes at sites under your control. Where the substance is distributed from your site neat, enter N/A for not applicable.

For example:

Category of Use	Formulated Product as Manufactured	Percent of Chemical Substance
Cross-linking agent for epoxy-type coatings for metal surfaces	none; distributed neat	N/A
Flame retardant for cotton apparel	none; distributed neat	N/A
Surfactant in automobile spray wax	spray auto wax (suspension)	4
Colorant for paper and other cellulosics	colorant (solution)	55

Column (7) — Mark (x) to indicate if the category of use is site-limited. Also mark (x) to indicate whether the use is for industrial, commercial, and/or consumer use as defined below. Mark more than one box, if appropriate. For example, a surfactant in an automobile wax may have a consumer use in liquid wax, a commercial use in auto washes, and an industrial use by automobile manufacturers.

Site-limited: The substance is used only on the contiguous property unit where it is manufactured and not intentionally distributed outside that site except for waste disposal. This includes all factories, storage space, and warehouses at the site. An example would be an intermediate which is further reacted on-site to produce a chemical product.

Industrial: The chemical substance or products containing the substance are used only at the site of other manufacturers or processors, e.g., textile dyeing, paint formulation, use of a resin to manufacture an article.

Commercial: The chemical substance or products containing the substance are used by a commercial enterprise providing a consumer service, e.g., use by commercial dry cleaning establishments, use by painting contractors, or use by roofers in commercial building construction.

Consumer: The chemical substance or products containing the substance are used by private individuals in or around a residence, or during recreation, or for any other personal use or enjoyment, e.g., automotive polish, dyed wearing apparel, household cleaners, etc.

Columns (2), (4), (6), (8) — Note that you must make separate confidentiality claims for the description of the category of use, the percent of production devoted to each category, and other use information. The information in this section is used to evaluate potential exposure of the chemical. If you wish to provide any additional information which would assist in this analysis, it may be submitted as optional information.

C. Hazard Information

Include with the form a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which is provided to any person regarding protective equipment or practices for the safe transport, use or disposal of the chemical. Identify any copies of hazard information or warnings that you attach in Part IV, List of Attachments.

D. Occupational Exposure Information

Column (1) — Describe each specific activity in the operation during which workers may be exposed to the chemical. Such activities may include charging reactor vessels, sampling for quality control, transferring materials from one work area to another, drumming, bulk loading, changing filters, and cleaning equipment. Activities must be described even if workers wear protective equipment or clothing. (Recommended protective equipment should be included as part of Hazard Information).

Column (3) — Indicate the physical form of the substance at the time of exposure, e.g., solid (crystals, granules, powder, dust), liquid (solution, paste, slurry, emulsion, mist, spray), gas (vapor, fume), even if workers wear protective equipment.

Column (5) — Report the maximum number of workers involved in each specific activity, based on the reported maximum 12-month production volume.

Column (7) — Enter the maximum duration that any one worker will engage in the activity in hours/day, e.g., 8 hours/day.

Column (8) — Enter the maximum duration that any one worker will engage in the activity in days/year, based on the reported maximum production volume, e.g., 200 days/year.

Columns (2), (4), (6), (9) — Note that you must make separate confidentiality claims for the description of worker activity, physical form of the chemical, number of workers exposed, and duration of exposure.

Part IV — List of Attachments

Attach any continuation sheets for sections of the form and any optional information, after the last page of the form. Clearly identify the attachment and the section to which it relates. Number consecutively the pages of the attachments. Enter the total number of pages in the form on the last line of the List of Attachments. Mark (x) the "Confidential" box next to any attachment you claim as confidential. See the section of these instructions titled Confidentiality for guidance on claiming any information confidential.

EPA Form 7710-51 (9-86)

BILLING CODE 6560-50-C

(e) Information collection requirements under this section approved by OMB are as follows:

Paragraph under § 766.35	Currently assigned OMB control No.
(b)(1)	2070-0054
(b)(2)	2070-0004
(b)(3)	2070-0017
(b)(4)(iii)	2070-0054
(c)(1)(i)	2070-0054
(c)(1)(ii)	2070-0004
(c)(1)(iii)	2070-0017

§ 766.38 Reporting on precursor chemical substances.

(a) *Identification of precursor chemical substances.* Precursor chemical substances are produced under conditions that will not yield HDDs and HDFs, but their molecular structure is conducive to HDD/HDF formation under favorable reaction conditions when they are used to produce other chemicals or products. The following precursor chemical substances are identified by Chemical Abstract Service (CAS) number and name.

CAS No.	Chemical name
85-22-3	Pentabromoethylbenzene.
87-61-6	1,2,3-Trichlorobenzene.
87-84-3	1,2,3,4,5-Pentabromo-6-chloro-cyclohexane.
89-61-2	1,4-Dichloro-2-nitrobenzene.
89-64-5	4-Chloro-2-nitrophenol.
89-69-0	2,4,5-Trichloronitrobenzene.
92-04-6	2-Chloro-4-phenylphenol.
94-74-6	4-Chloro-o-toloxy acetic acid.
94-81-5	4-(2-Methyl-4-chlorophenoxy) butyric acid.
95-50-1	o-Dichlorobenzene.
95-56-7	o-Bromophenol.
95-57-8	o-Chlorophenol.
95-88-5	4-Chlororesorcinol.
95-94-3	1,2,4,5-Tetrachlorobenzene.
97-50-7	5-Chloro-2,4-dimethoxyaniline.
99-30-9	2,6-Dichloro-4-nitroaniline.
99-54-7	1,2-Dichloro-4-nitrobenzene.
106-46-7	p-Dichlorobenzene.
108-70-3	1,3,5-Trichlorobenzene.
108-86-1	Bromobenzene.
108-90-7	Chlorobenzene.
117-18-0	1,2,4,5-Tetrachloro-3-nitrobenzene.
120-82-1	1,2,4-Trichlorobenzene.
348-51-6	o-Chorofluorobenzene.
350-30-1	3-Chloro-4-fluoronitrobenzene.
615-67-8	Chlorohydroquinone.
626-39-1	1,3,5-Tribromobenzene.
827-94-1	2,6-Dibromo-4-nitroaniline.

(b) *Persons required to report.* All persons who manufacture or import a chemical product produced using any of the chemical substances listed in paragraph (a) of this section as feedstocks or intermediates must report no later than September 29, 1987. Small manufacturers and those manufacturers and importers who produce the precursor chemical substances in quantities of 100 kilograms or less per year only for research and development purposes are not required to report under this section

(c) *Data to be reported.* Manufacturers and importers of chemical products made from precursor chemical substances identified in paragraph (a) of this section must report process and reaction condition data on Part II of form EPA 7910-51 (appearing at § 766.35(d) for each such chemical product. A separate form EPA 7910-51 must be submitted for each chemical product reported, and the precursor chemical substance used must be identified. All forms must be submitted to EPA no later than September 29,1987.

(Approved by the Office of Management and Budget under control number 2070-0054.).

[FR Doc. 87-12586 Filed 6-4-87; 8:45 am]

BILLING CODE 6560-50-M

Alternative Methodology for
Acute Toxicity Testing

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SEP 22 1988

Re: Revised Policy for Acute Toxicity Testing

Appended is a revised policy for evaluating the acute toxicity of chemical exposures under the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act. This action builds upon a previous revision of the acute toxicity testing strategy to reduce the use of experimental animals while providing adequate information about chemical safety.

The Environmental Protection Agency is disseminating this notice to industry, governmental bodies, scientific societies, animal welfare groups and interested parties to apprise them of our new position. The Agency's acute toxicity testing guidelines are being revised to reflect the positions articulated in this policy.

Victor J. Kimm
Acting Assistant Administrator
for Pesticides
and Toxic Substances

Enclosure

Alternative Methodology for Acute Toxicity Testing

The Environmental Protection Agency announces a revision to its approach to acute toxicity testing in fulfillment of actions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). This revision reflects the Agency's concern about animal welfare and its continued efforts to reduce the impacts on animals of EPA's testing requirements. While maintaining the tiered approach adopted in 1984, the Agency now recommends (when appropriate) the use of abbreviated test methods and consideration of using only one sex, as a means of reducing the numbers of animals in deriving important information on acute toxicity.

Background

EPA considers the evaluation of toxicity following short-term exposure to a chemical (i.e., acute toxicity) to be a limited but integral step in the assessment of the toxic potential of a chemical substance under the regulatory framework of its pesticide and toxic substances programs. The Agency also supports measures dedicated to reduce the use of animals in toxicity testing and conducts research on test methods which can lead to further reduction or elimination of animal usage and suffering. Through the careful selection of test methodology and maximization of the data obtained from acute studies, EPA strives to achieve a balance between the welfare of animals and the need to utilize animals in evaluating chemical safety.

The approach to acute toxicity testing previously given in EPA's Test Guidelines (U.S. Env. Prot. Agency, 1978; 1979) emphasized the determination of the median lethal dose (LD50) with a 95% confidence interval. A 1984 update of the guidelines,

published in 1985 (U.S. Env. Prot. Agency, 1985) stated that the Agency discouraged the uses of the "classical" LD50 test employing large numbers of animals for determination of lethality only. Instead, the Agency emphasized the use of a tiered approach to obtain acute toxicity data which reduced the number of animals used, but maximized the amount of relevant information that could be obtained from such testing. That approach included the following:

a. Using Data From Structurally Related Chemicals. The Agency encourages the review of existing acute toxicity information on chemical substances that are structurally related to the agent under investigation. Using this approach, one may be able to compile enough information from these surrogate chemicals to make preliminary safety evaluations that reduce the need for further animal testing or which indicate the type of testing to be pursued.

b. "Limit" Test. When information on structural analogs is inadequate, one should consider the "limit" test. The relative toxicity of a chemical is determined by professional judgement; for chemicals judged to be relatively non-toxic, a single group of animals is given a large dose of the agent. If no lethality is demonstrated, no further testing for this information is pursued.

c. Multifaceted Testing. A three-dose multiple endpoint evaluation may be important for those substances judged to be relatively toxic or which demonstrate lethality in the limit test. Using this procedure, animals are evaluated as to the onset, duration, intensity, and reversibility of behavioral effects, body weight changes and lethality; all animals are submitted to gross necropsy. Histopathology and certain follow-up studies may be warranted where there are gross indications of target organ toxicity.

Present Revision.

EPA has reevaluated its data needs on acute toxicity and continues to espouse the tiered approach that was developed in the 1984 update. Thus, the first consideration for a chemical for which there is no acute toxicity data, should be a review of structurally related compounds, followed by the limit test when appropriate. In those cases where testing beyond the limit test is indicated, consideration should be given to well-designed abbreviated test schemes which employ minimal numbers of animals, as discussed below. In most cases, it is expected that these tests can be structured to give enough information on acute toxicity to obviate the need for further acute studies (e.g., the three-dose multi-faceted testing approach). We continue to stress the need for collecting information on behavioral effects, gross pathology and lethality (as developed in "c" above).

While more complete animal testing may be necessary in some cases (based on scientific evidence from the abbreviated test, e.g., delayed toxicity, unusual central nervous system effects, irreversible effects), the Agency generally supports limiting such tests to those using the lowest feasible number of animals.

Several abbreviated methods to investigate acute toxicity have been developed over the years. Some of them have rather extensive data bases and have been validated against more traditional test methods which estimate median lethal dose. Their merit lies in the fact that they allow for the evaluation of the full spectrum of acute responses; numerical calculations can be made; and fewer animals may be employed in the generation of the information than with most other approaches. For some methods, statistical calculations are simple or are aided by tables.

EPA has investigated four methodologies that might be used. These include (1) the approximate lethal dose method[1] of Deichmann and Le Blanc (1943); (2) the moving averages method[2] of Thompson (1947); (3) the up-and-down method[3] of Dixon and Mood (1948) and Dixon (1965); and (4) the cumulant method of Reed-Muench[4] (1938).

The methods vary as to the assumptions that are made, the number of groups of animals and number of animals per group. Toxicologists should be familiar with these differences before employing a given method. For instance, the up-and-down method is especially difficult to apply when chemicals induce delayed toxic effects. Therefore, other methodologies may be more appropriate. When an alternative method for acute toxicity testing is selected, a rationale for such a selection should accompany the submission. The Agency solicits discussions with data generators on still other methods that may be employed.

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[1]The approximate lethal dose method was further refined by Deichmann and Mergard (1948); these authors performed eighty-seven determinations (calculated by the methods of Behrens (1929) and Bliss (1938)). The approximate lethal dose method was also used by Kennedy et al. (1986).

[2]The moving averages method was refined by Weil (1952, 1983) and Gad and Weil (1982), and was used by Smythe and Carpenter (1944, 1948) and Smythe et al. (1949, 1951, 1954, 1962).

[3]The up-and-down method was recently used and refined by Bruce (1985, 1987) (calculated by the method of Bliss (1938)). The up-and-down method was also used by Brownlee et al. (1953), Dixon and Massey (1957), Klassen and Plaa (1967) and Hsi (1969).

[4]The Department of Defense has had considerable experience using the Reed-Muench method with a large number of chemicals (F. Vocci, personal communication); it has also been used by Lorenz and Bogel (1973), Bhan (1974), Aubert and Amdral (1979), and Thakur and Fezio (1981).

The Agency emphasizes that parallel assays on male and female animals to determine an approximate estimate of acute toxicity need not be routinely determined, since male and female animals of the same strain generally show only slight and insignificant differences in susceptibility to toxic agents. However, for some chemicals, one sex may be somewhat more sensitive than the other (Muller and Kley (1982); Schutz and Fuchs (1982); (Bruce (1985)). Cassarett and Doull (1980) indicate that the class of compound is important in specific sex differences. De Pass et al. (1984) showed that for 91 chemicals tested for oral toxicity in rats, females were slightly more sensitive than males ($p<.001$). Muller and Kley (1982) performed 152 parallel studies on male and female animals for which 129 showed no significant differences. However, when statistically significant differences were observed (23 compounds), 17 were more toxic to females. Therefore, consideration should be given to limiting studies to the more sensitive sex. Previous history on the class of chemical being evaluated would be helpful in making this determination. For confirmation, a few animals of the other sex should also be tested.

In summary, EPA has modified its approach to acute toxicity testing, recognizing that appropriate information for safety evaluation can be developed using fewer animals than had been recommended in the past. We strongly urge industry to use these abbreviated test methodologies, whenever appropriate, as replacements for the three-dose multifaceted method EPA previously had recommended. Four such methodologies which might be used have been identified; other methods may also be employed, if adequate rationale can be provided. It is expected that studies will still include behavioral observations, gross necropsy and ancillary observations, as before.

EPA urges industry to begin submitting data obtained with alternate methods which use fewer animals on a routine basis; the Agency is planning to revise its testing guidelines to incorporate the above guidance. We plan to accept only newly generated industry data that conforms with our revised guidance unless an adequate rationale (e.g., data generated in accordance with regulatory requirements other than those of EPA) accompanies the submission; data without a rationale may be returned to the submitter.

The Agency encourages the public to comment on this position and provide information on still other alternate methodologies which have progressed to a stage of validation which would be acceptable to the scientific community.

References

Aubert M.F.A. and Amdral L. (1979). Potency Testing of Veterinary Vaccines Containing Inactivated Virus. Comp. Immunol Microbiol. Infect. Dis., 1, 341-349.

Behrens B. (1929). The Assay of Digitalis on Frogs. Arch. Exptl. Path. Pharmakol., 140, 237-256.

Bhan A.K. (1974). Computing LD50 More Efficiently and Accurately - A Modification of Reed-Muench Method. Indian Soc. Nucl. Agricul. Biol., 3, 5-6.

Bliss C.I. (1938). Determination of the Small Dosage Mortality Curve from Small Numbers. Quart. J. Year Book Pharm., 11, 192-216.

Brownlee K.A., Hodges J.L. and Rosenblatt M. (1953). The Up-and-Down Method With Small Samples. Amer. Statist. Assoc. J., 48, 262-277.

Bruce R.D. (1985). An Up-and-Down Procedure for Acute Toxicity Testing. Fundam. Appl. Toxicol., 5, 151-157.

Bruce R.D. (1987). A Confirmatory Study of the Up-and-Down Method for Acute Oral Toxicity Testing. Fundam. Appl. Toxicol., 8, 97-100.

Casarett L.J. and Doull J. (1980). Factors Influencing Toxicology. In: Toxicology, The Basic Science of Poisons, J. Doull, C.D. Klaasen and M.O. Amdur, eds., 77-88. New York: Macmillan Publishing Co., Inc.

Deichmann W.B. and LeBlanc T.L. (1943). Determination of the Approximate Lethal Dose With About Six Animals. J. Indust. Hyg. Toxicol., 25, 415-417.

Deichmann W.B. and Mergard E.G. (1948). Comparative Evaluation of Methods Employed to Express the Degree of Toxicity of a Compound. J. Indust. Hyg. Toxicol., 30, 373-378.

De Pass L.R., Myers R.C., Weaver E.V. and Weil C.S. (1984). An Assessment of the Importance of Number of Dosage Levels, Number of Animals per Dosage Level, Sex and Method of LD50 and Slope Calculation in Acute Toxicity Studies. In: Acute Toxicity Testing: Alternative Approaches, A.M. Goldberg, ed. (Alternative Methods in Toxicology, Vol. 2), 142-153. New York: Mary A. Liebert, Inc., Publisher.

References (contd.)

Dixon W.J. (1965). The Up-and-Down Method for Small Samples. Amer. Statist. Assoc. J., 60, 967-978.

Dixon W.J. and Massey F.J. Jr. (1957). Sensitivity Experiments, In: Introduction to Statistical Analysis, 318-327. New York: McGraw-Hill.

Dixon W.J. and Mood A.M. (1948). A Method for Obtaining and Analyzing Sensitivity Data. Amer. Statist. Assoc. J., 43, 109-126.

Gad S.C. and Weil C.S. (1982). Statistics for Toxicologists. In: Methods in Toxicology, A.W. Hays, ed., 273-309. New York: Raven Press.

Hsi, B.P. (1969). The Multiple Sample Up-and-Down Method in Bioassay. Amer. Statist. Assoc. J., 64, 147-162.

Kennedy, G.L. Jr., Ferenz, R.L. and Burgess, B.A. (1986). Estimation of Acute Oral Toxicity in Rats by Determination of the Approximate Lethal Dose Rather Than the LD50. J. Appl. Toxicol. 6, 145-148.

Klassen, C.D. and Plaa, G.L. (1967). Relative Effects of Various Chlorinated Hydrocarbons on Liver and Kidney Function in Dogs. Toxicol. Appl. Pharmacol., 10, 119-131.

Lorenz R.J. and Bogel K. (1973). Methods of Calculation. Method of Reed and Muench. Laboratory Techniques in Rabies. WHO Monograph Series 23, 3rd Ed., 329-335.

Muller H. and Kley H.P. (1982). Retrospective Study on the Reliability of an "Approximate LD50"[5] Determined with a Small Number of Animals. Arch. Toxicol., 51, 189-196.

Reed L.J. and Muench H. (1938). A Simple Method for Estimating Fifty Percent Endpoints. Amer. J. Indust. Hyg. Toxicol., 30, 373-378.

Schutz E. and Fuchs H. (1982). A New Approach to Minimizing the Number of Animals Used in Acute Toxicity Testing and Optimizing the Information of Test Results. Arch. Toxicol., 51, 197-220.

Smythe H.F. Jr. and Carpenter C.P. (1944). Place of the Range-Finding Test in the Industrial Toxicology Laboratory. J. Indust. Hyg. Toxicol., 26, 269.

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[5] "Approximate LD50" in the title of this paper is placed in quotation marks so as not to confuse it with the method of Deichman and Le Blanc (1943).

References (contd.)

Smythe H.F. Jr. and Carpenter C.P. (1948). Further Experience with the Range-Finding Test in the Industrial Toxicology Laboratory. J. Indust. Hyg. Toxicol., 30, 63.

Smythe H.F. Jr., Carpenter C.P. and Weil C.S. (1949). Range-Finding Toxicity Data: List III. J. Indust. Hyg. Toxicol., 31, 60.

Smythe H.F. Jr., Carpenter C.P. and Weil C.S. (1951). Range-Finding Toxicity Data: List IV. AMA Arch. Indust. Hyg. Occ. Med., 4, 119.

Smythe H.F. Jr., Carpenter C.P., Weil C.S. and Pozzani U.C. (1954). Range-Finding Toxicity Data: List V. AMA Arch. Indust. Hyg. Occ. Med. 10, 61.

Smythe H.F. Jr., Carpenter C.P., Weil C.S., Pozzani U.C., and Striegel J.A. (1962). Range-Finding Toxicity Data: List VI. Amer. Indust. Hyg. Assoc. J., 23, 95.

Thakur A.K. and Fezio W.L. (1981). A Computer Program for Estimating LD50 and It's Confidence Limits Using Modified Behrens-Reed-Muench Cumulant Method. Drug Chem. Toxicol., 4, 297-305.

Thompson, W.R. (1947). Use of Moving Averages and Interpolation to Estimate Median Effective Dose. Bacteriol. Rev. 11, 115-145.

U.S. Environmental Protection Agency. (1978). Proposed Guidelines for Registering Pesticides in the U.S. Hazard Evaluation: Humans and Domestic Animals. Fed. Reg. 43, 37336-37345; 37351-37356. (August 22).

U.S. Environmental Protection Agency. (1979). Proposed Health Effects Test Standards for Toxic Substances Control Act Test Rules and Proposed Good Laboratory Practice Standards for Health Effects. Fed. Reg. 44, 44054-44059; 44066-44067. (July 26).

U.S. Environmental Protection Agency. (1985). Health Effects Testing Guidelines. Fed. Reg. 50, 39397-39398. (September 27)

Vocci. F. (1988). Personal Communication (Unpublished Data).

Weil C.S. (1952). Tables for Convenient Calculation of Median Effective Dose (LD50 or ED50) and Instructions on Their Use. Biometrics 8, 249-263.

Weil C.S. (1983). Economical LD50 and Slope Determinations. Drug Chem. Toxicol. 6, 595-603.

For general information and/or additional copies please call:

202-354-1404

For technical information call:

703-557-7492
Dr. Rinde