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Toxic Substances

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EPA

Section 4 of the Toxic Substances Control Act: An Overview

Test Rules
Development Branch
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SECTION 4 OF THE TOXIC SUBSTANCES CONTROL ACT: AN OVERVIEW[1]

A. INTRODUCTION

Section 4 of the Toxic Substances Control Act (TSCA) was enacted by Congress to respond to the concern that effects of chemical substances and mixtures on human health and the environment were frequently inadequately documented and understood. This section of TSCA gives the Administrator of the Environmental Protection Agency (EPA) the authority to require the development of adequate test data on the health and environmental effects of potentially hazardous chemicals. These data help the Administrator, other Federal agencies, and state and local governments, to determine both whether and how to regulate or control potentially hazardous chemicals.

The primary purpose of this overview is to describe EPA's policies and procedures for implementing its section 4-related responsibilities. It provides a general introduction to: the objectives and requirements of section 4; the statutory constraints affecting EPA's decisionmaking process; the alternative processes by which EPA may ensure necessary testing is done; and the key opportunities for public involvement in the section 4 process.

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[1]Much of the material contained in this Overview Package was developed by Jellinek, Schwartz, Connolly & Freshman, Inc., Washington, D.C., under the supervision of the Test Rules Development Branch, pursuant to EPA Contract No. 68-02-4214.

B. OBJECTIVES AND REQUIREMENTS OF SECTION 4

Section 4 of TSCA was designed to ensure the following: (1) Chemicals which may pose "unreasonable" risks of health or environmental damage, or may involve substantial production or exposure, receive priority attention for testing. (2) EPA has the authority to require chemical manufacturers and processors to perform testing on such chemicals. This section of the Act requires that EPA make three findings before requiring the manufacturers and/or processors of a chemical to test it for the potent effects of concern to the Agency.

Specifically, EPA must make all of the following findings:

(1) that the chemical may pose an "unreasonable risk" to health or to the environment; or that the chemical is produced in "substantial" quantities, which could result in substantial or significant human exposure or substantial environmental release; and

(2) that insufficient data or knowledge exist about the health or environmental effects of the chemical to reasonably determine or predict the impacts of its manufacture, processing, distribution, use and/or disposal; and

(3) that testing is needed to develop such data.

Additionally, EPA considers the potential economic impacts of the required testing before issuing requirements under section 4.

C. EPA'S ALTERNATIVES FOR ENSURING THE NECESSARY TESTING IS DONE

If EPA makes all of the above findings for a specific chemical or category of chemicals, EPA may issue a test rule requiring industry to test the substance(s).

Alternatively, if EPA finds that affected manufacturers and processors, and interested members of the public agree with the Agency regarding the need for and scope of testing requirements, EPA may issue an enforceable consent order to expedite the testing.

If a consensus of the interested parties cannot be reached, e.g., because testing issues are in dispute or are too complicated to be resolved in the limited time available, the Agency will initiate rulemaking.

D. CONSTRAINTS IMPOSED BY INTERAGENCY TESTING COMMITTEE'S RECOMMENDATIONS

TSCA established the Interagency Testing Committee (ITC) to help EPA determine which chemicals should receive priority attention under the testing provisions of the Act. The ITC is comprised of representatives of EPA and several other federal agencies that are involved in regulation and research related to environmental and health issues. The ITC reviews readily available data on a variety of chemicals; it also recommends substances which may require additional testing for EPA's priority consideration. The ITC presents these recommendations in the form of the TSCA Section 4(e) Priority List ("Priority List").

The Priority List of chemicals is divided into three parts: 1) those designated for EPA response within 12 months; 2) those recommended with intent-to-designate; and 3) those recommended without being designated for

response within 12 months. (Chemicals in the first part are called designated chemicals; chemicals in the second and third parts are non-designated chemicals.)

When the ITC designates a chemical for priority consideration, TSCA requires that EPA must either initiate rulemaking to require testing of the chemical, or publish its reasons for not so doing within one year. (No more than fifty chemical substances may be designated at any one time.)

The ITC recommends with intent-to-designate chemical substances or mixtures which it believes should receive expedited testing consideration, by means of the second part of the Priority List. The ITC may designate these chemicals later, after EPA's review of the Committee's testing recommendations, and after the ITC's own review of the data collected under TSCA sections 8(a) and 8(d) and other relevant information. The intent-to-designate recommendation does not require EPA to respond to the ITC by a certain deadline. Should these chemicals be subsequently designated, a one-year statutory deadline for EPA response would be imposed at that time.

The third part of the Priority List includes chemical substances or mixtures that the ITC believes warrant testing consideration, but not expedited review of testing needs. The ITC adds the chemical substance or mixture to the Priority List, and recommends it for testing without designating the substance or mixture for EPA review within any statutory deadline. These chemicals may be evaluated by EPA as time and resources permit.

E. EPA'S RESPONSE TO ITC RECOMMENDATIONS

The Test Rules Development Branch (TRDB) of EPA's Office of Toxic Substances (OTS) has the lead responsibility for carrying out the Agency's section 4-related activities. After the ITC's recommendation of chemicals for testing, OTS analyzes the available information, obtains additional information, determines whether additional testing is needed and whether the available data support the required section 4 regulatory findings, obtains both technical and policy review of a consent agreement or a proposed testing program, and prepares the necessary Federal Register notices. Because of the many tasks involved in testing decisions, OTS has found it necessary to establish very tight deadlines for obtaining and evaluating relevant information, and for arriving at preliminary testing decisions for approval by upper-level Agency management.

If the ITC designates a chemical for consideration by EPA, the Agency must respond within the one-year statutory deadline. EPA's section 4 process has been carefully designed to include a series of interim deadlines and decision points. This schedule is intended to ensure that the statutory one-year deadline will be met, and to provide sufficient opportunity for both public input and for the Agency's internal review of proposed testing decisions. One critical milestone occurs approximately 18 to 20 weeks after EPA's receipt of the ITC's designations. At that time, a preliminary decision must be made by EPA staff as to whether testing of a given chemical is needed, and for what effects. If EPA determines that testing is needed, it will proceed with the development of a proposed test rule for the chemical. EPA does not use the consent agreement process for designated chemicals because of the short time frame available to meet the

statutory deadline. It is therefore crucial that all data relevant to this "course-setting" decision be submitted to the Agency considerably earlier than the 18th week. Such data may include information on the production, use, exposure, environmental release, health effects, or environmental effects of a chemical.

If the ITC recommends with intent-to-designate a chemical (or mixture), EPA conducts a similar evaluation of the chemical. However, in addition to the rulemaking procedures described above, EPA has the consent agreement[2] option for chemicals that have been recommended with intent-to-designate. To use the consent agreement process, EPA determines whether a consensus exists among the Agency, industry, and other interested individuals, regarding the need for and scope of testing.

A major milestone of the consent agreement process is the deadline by which a tentative consent agreement must be established. By week 32, EPA, industry, and interested public groups must reach a consensus regarding the need for and scope of required testing. This deadline is particularly important, because if there is no consensus, the consent agreement option is extinguished and EPA must proceed with the issuance of a proposed test rule. Chemicals in the recommended with intent-to-designate category may also proceed directly to rulemaking when EPA believes individual chemical substance or mixture testing requirements cannot be successfully negotiated through the consent agreement process.

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[2]A consent agreement is an agreement between EPA and interested parties, who agree either to conduct testing or to a test program. Once the agreement is signed by all parties, it is known as a consent order, which is legally binding and enforceable.

If the ITC recommends a chemical or mixture for testing consideration by EPA without designating it for EPA response within one year, the Agency will evaluate the chemical according to its relative priority versus that of all other ITC chemicals. There is no deadline for response by EPA for these chemicals; both rulemaking and consent agreement options are available.

EPA also develops testing requirements under the Act for chemicals that warrant testing even though they have not been recommended by the ITC. These non-ITC chemicals are considered for test rules or consent agreements in cases where the Office of Toxic Substances, or another EPA program, needs test data to assess the risks of the chemical. The schedules for the development of test rules and consent agreements for non-designated ITC chemicals are generally followed for these chemicals.

The following section chronologically presents some of the key interim decision points and deadlines in EPA's section 4 process, as well as points at which public input to the process is sought.

F. KEY DECISION POINTS AND OPPORTUNITIES FOR PUBLIC INVOLVEMENT IN EPA'S SECTION 4 PROCESS

This section will enable interested parties to effectively participate in EPA's section 4 process by detailing where in the process critical interim decisions are made, and when public comments on the approach or on tentative decisions are solicited.[3] The course-setting decision point is

[3]An opportunity also exists for public input during the ITC's consideration of chemicals for the Priority List, i.e., when the preliminary list of chemicals being considered by the ITC for addition to the Priority List is published in the Federal Register.

highlighted by a double asterisk (**). The end of the reporting period for public submission of section 8(a) and section 8(d) information is the deadline by which interested parties must submit their views and any relevant information, in order to receive consideration prior to the Agency's preliminary decisions. The week numbers represent target dates. A summary chart of section 4 process target dates is located at the end of this booklet.

Week Number

0-2 Receipt and Publication by EPA of the ITC Recommendation on a Given Chemical

EPA's receipt of the ITC's recommendations initiates the section 4 process. For those chemicals designated by the ITC for testing consideration, a one-year deadline is established for the Agency to respond with a regulatory decision.

Approximately two weeks after receipt of the ITC recommendations, EPA publishes a Federal Register notice which:

- announces EPA's receipt of the ITC report;
- establishes a four-week period for submission of public comments on the ITC's recommendations (the first of several opportunities for public input);
- invites the public to attend Focus Meetings (see week 6 below) as well as subsequent public meetings (see week 22 below)[4]; and
- in cases of chemicals under consideration for consent agreements,

[4]The date and location of the Focus Meeting for each chemical is indicated in the Federal Register notice. The notice states that parties interested in attending subsequent public meetings should contact EPA to request notification of the dates and locations of these meetings.

invites persons interested in participating in or monitoring the negotiations of the consent agreement to contact the Agency in writing.

In addition to publishing the ITC report, EPA issues TSCA section 8(a) and 8(d) reporting rule amendments in the Federal Register, under the automatic reporting rule promulgation procedures of 40 CFR Part 712, and 40 CFR Part 716, respectively. The TSCA section 8(a) Preliminary Assessment Information rule requires manufacturers to submit specific production and exposure information on the ITC-designated and ITC-recommended chemicals within 90 days of publication of the amendment. The TSCA section 8(d) Health and Safety Data Reporting rule requires manufacturers, processors, and distributers who possess or know of such studies to submit copies or lists of unpublished health and safety studies on the ITC-designated and ITC-recommended chemicals within 90 days of publication of the amendment. The section 8(d) rule also requires such persons to notify EPA if they subsequently initiate a health or safety study on a listed chemical. Persons subject to these reporting requirements are urged by EPA to submit such information as early as possible in the reporting period. The public docket for the chemical is also established at this time; its location and the public hours for review are announced in the Federal Register.

3-6 Comment Period on the ITC Report

The public is invited to submit comments on the ITC Report during this time.

6-18 Discussion Phase

At this point, EPA begins discussions with the affected industry and other interested parties to exchange information and to allow an opportunity for the public to provide input to the Agency's decision-making process. Usually EPA holds a public focus meeting to begin these discussions. This meeting helps focus the Agency's inquiry and highlights the issues of greatest importance to EPA and other interested parties.

7-14 Public Submission of Relevant Information/Section 8(a) and 8(d) Reporting Period

During the weeks prior to EPA's tentative decision on the need to require testing (see week 18 below), specific information is requested from all interested parties regarding the need for further testing and, if appropriate, what types of tests should be required for the chemical in question. These early weeks are the critical time for the public to submit information relevant to EPA's testing decisions, and for industry to submit information in response to section 8(a) and 8(d) reporting requirements.

** 18-20 Course-Setting Decision

At this point, EPA makes preliminary internal decisions, known as "course-setting" decisions, as to whether testing of the chemical is warranted, and for what effects. These preliminary decisions are based on the ITC recommendations, public data submissions, information received as a result of the public focus meeting, and Agency's own preliminary evaluations of production, use, exposure, health, and environmental data.

22 Public Meeting on Course-Setting and Deadline for Requests to Participate in Consent Agreement Negotiations

EPA holds a public meeting to announce its preliminary course-setting decisions and the basis for those decisions. The public is invited to comment on EPA's preliminary decisions. These preliminary decisions may be altered, if necessary, based on additional analysis resulting from public comment. In addition, for non-designated chemicals, individuals interested in participating in any consent agreement negotiations must also notify EPA in writing by this time. For designated chemicals, EPA does not initiate negotiations, but proceeds directly to preparation of a proposed rule to require the necessary testing (see week 52 below).

22-30 Negotiation of Consent Agreement (Non-Designated Chemicals Only)

During this period, EPA meets with affected manufacturers and processors, and other interested parties, to determine whether a preliminary agreement on a testing program can be reached. Individuals and groups who have responded by week 22 to EPA's initial Federal Register notice (see weeks 0-2 above) are designated "interested parties" and are afforded an opportunity to participate in the negotiation process at their own expense. All negotiation meetings are open to members of the public, who may observe. EPA advises interested parties of meeting dates and circulates meeting minutes, testing proposals, background documents, and other relevant materials.

32 EPA Decision Point: Consent Agreement or Test Rule

By week 32, EPA determines whether a tentative agreement can be reached on a testing program acceptable to EPA, and whether continued

negotiation is likely to result in a draft agreement within an additional 4 weeks. If both stipulations are affirmative, EPA proceeds with the development of an agreement. If a tentative agreement has not been reached and it appears unlikely that additional negotiation will result in such an agreement by week 36, EPA proceeds with the development and preparation of a proposed test rule (to be published by week 62).

32-36 Preparation of Consent Agreement

If a consensus is reached, EPA prepares a draft agreement that reflects the apparent consensus, which contains suitable guidelines as the required testing standards. The agreement is then distributed to the interested parties for comment.

42 Optional Meeting to Address Comments on the Draft Consent Agreement

If necessary, EPA will hold a public meeting to address comments received in response to the draft consent agreement.

42-44 Preparation of the Consent Order and Federal Register Notice

After the comment period for the agreement, EPA prepares the consent order (which incorporates the consent agreement). Each consent order is accompanied by a support document which explains the basis for the original agreement, summarizes any ITC testing recommendations for the chemical, describes the objectives of the testing to be conducted and the rationale for the selection of tests, and briefly outlines the use and exposure characteristics of the test chemical. This support document will become a part of the record and will serve as the basis for the consent order.

48 Signature of Consent Order

The consent order is circulated for signature by the Agency and the interested parties. The consent order becomes legally enforceable as of its effective date.

50 Publication of Consent Order Notice in Federal Register

When a consent order has been issued, the document explaining the basis for the consent order and a notice of availability of the consent order itself is published in the Federal Register. This notice serves as the statement of EPA's reason for not initiating rulemaking under section 4 of TSCA.

52-62 Publication of Decision Not to Require Testing

If EPA determines that no testing of a chemical is necessary, the Agency will prepare a Federal Register notice to respond to the ITC, which describes why EPA has determined that further testing is not required.

52-62 Publication of Proposed Rule

If EPA determines that testing of a designated chemical is necessary (or that timely consensus will not be reached for a non-designated chemical), the Agency pursues development of a rule to require testing of the chemical. A proposed test rule is signed by week 52 to initiate rulemaking for designated chemicals, or by week 62 for chemicals recommended with intent-to-designate. The proposed test rule specifies the chemical to be tested, health and environmental effects for which testing will be required, proposed test standards for the development of test data, schedules for the submission of test data, and who is responsible for conducting the testing. The

Agency usually proposes the TSCA Test Guidelines, or other suitable guidelines, as the required test standards for the rule. The guidelines are modified as necessary, to allow for specific characteristics of the chemical to be tested. The public is invited to comment on the proposed rule during a 60-day period.[5]

To initiate rulemaking, the Agency may choose in some cases to issue an Advance Notice of Proposed Rulemaking (ANPR) rather than a proposed rule. This alternative is generally used when an ITC-designated chemical or chemical category presents complicated issues on which the Agency seeks public comment early in the rulemaking process. EPA publishes the ANPR at approximately week 52 (or 62), following receipt of the initial ITC report. This is followed by a

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[5]For certain test rules, EPA may use a two-phase rulemaking process. Generally, EPA uses the two-phase process in cases where no well-accepted test methodology is available for inclusion in a proposed test rule. Under two-phase rulemaking, the Agency issues a proposed rule at week 52 or 62 specifying the chemical to be tested, the effects for which testing is required, and who is responsible for conducting testing. This is a Phase I proposed test rule. The public is invited to comment on the proposed rule during a 60-day period. After consideration of public comments, EPA publishes a Phase I final test rule at week 108. The rule becomes effective approximately 44 days after its publication in the Federal Register. The rule requires each person subject to it to submit, within 30 days after the effective date of the rule, either a letter of intent to conduct the testing or an application for exemption. Test standards and schedules are developed in a second phase of rulemaking. In the second phase of two-phase rulemaking, test sponsors are required to submit proposed study plans for the required tests within 90 days after the effective date of the Phase I final test rule. The study plans submitted by industry in response to a Phase I test rule, with any modifications considered necessary by the Agency, are proposed for comment in the Federal Register. After providing a 45-day comment period and an opportunity for a public meeting on the sponsors' proposed test study plans, EPA adopts the study plans, as proposed or modified, as specific test standards and schedules for the test rule. This is a Phase II test rule. After EPA publishes a Phase II final rule that adopts test standards and schedules for a test rule, industry is required to perform the testing according to the schedule specified in the rule. EPA announces in the Federal Register the receipt and availability of data from testing performed under a test rule.

proposed rule or decision-not-to-test which is published by week 108. A final rule or notice terminating the rulemaking process is published by week 154.

70-106 Preparation of Final Rule or Decision Not to Test

In response to public comments received on the proposed rule, EPA prepares either a final test rule or a decision not to require testing.

08 Publication of the Final Test Rule in the Federal Register

Once EPA publishes a final test rule, each person subject to the rule must submit either a letter of intent to conduct the testing or an application for exemption within 30 days after the effective date of the rule. Test sponsors are required to commence testing and to submit test data according to the schedule specified in the rule. Study plans must be submitted to EPA at least 45 days before the start of each test. EPA will inspect the testing laboratory and audit the study data as appropriate to ensure that the study is conducted in conformance with the study plan and EPA Good Laboratory Practice standards.

G. TEST DATA SUBMITTED IN COMPLIANCE WITH A CONSENT ORDER OR TEST RULE

When the Agency receives data which are submitted in compliance with a consent order or test rule, EPA publishes a Receipt of Data Notice in the Federal Register. This notice appears within 15 days of receipt of the data to announce their availability. The notice identifies the type of test data received, when they were received, and the EPA action in response to which they were submitted.

Test data are reviewed by EPA to determine their completeness and reliability, and to ensure that the data were submitted in compliance with the test rule requirements. After this preliminary review, the data are further evaluated to assess their adequacy for use in an evaluation of the risks associated with the chemical. Should some regulatory or other action appear warranted, the data on the chemical are referred to the appropriate office within EPA.

H. FURTHER INFORMATION ON THE SECTION 4 PROCESS

For specific information on EPA's section 4 activities on particular chemicals, and for more information on the section 4 process, interested parties should contact the TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M Street, S.W., Washington, D.C. 20460. Toll Free: (800-424-9065); in Washington, D.C.: (544-1404); outside the United States: (Operator-202-554-1404).

TARGET SCHEDULE FOR EPA ACTION: SECTION 4 PROCESS

NOTIFICATION AND INFORMATION GATHERING, EXCHANGE, AND ANALYSIS

Week[6]	Event
0	Receive ITC Report
2	Publish ITC Report & 8(a) & 8(d) Notices; Invite Public Participation in Negotiations
*3-6	Comment Period on ITC Report
*6-18	Discussion Phase
7-14	8(a) and 8(d) Reporting Period
*22	Public Meeting on Course-Setting Decision; Deadline for Request to Participate in Negotiations
22-30	Negotiation of Enforceable Consent Agreement[7]
32	Decision Point: Consent Agreement or Test Rule

CONSENT AGREEMENT		TEST RULE	
36-40	Comment Period	32-60	Prepare Test Rule; Agency Review and Signing
42	Meeting to Address Comments (if necessary)	52-62	Publish Proposed Rule in FR
48	Signing of Consent Order and FR Notice	70-106	Agency Review of Comments; Prepare Final Rule or No-Test Decision; Agency Review of Rule; Signing of Rule
50	Publish FR Notice	108	Publish Final Rule or No-Test Decision in FR

FR = Federal Register
* Points in the process when public comment is solicited.

[6]The dates contained in the left-hand column are calculated from the date EPA receives the ITC report recommending a chemical for testing.

[7]Designated chemicals do not go through the negotiation process, but proceed directly from week 22 to test rule preparation, and are signed by week 52.