United States
Environmental Protection
Agency

Office of Pesticides
and Toxic Substances
Washington, DC 20460

Toxic Substances

December 198

EPA

Section 4 of the Toxic Substances Control Act: An Overview

Test Rules Development Branch Office of Toxic Substances

SECTION 4 OF THE TOXIC SUBSTANCES CONTROL ACT: AN OVERVIEW

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A. INTRODUCTION

Section 4 of the Toxic Substances Control Act (TSCA) was enacted by Congress in response to the concern that, in many cases, the effects of chemical substances and mixtures on human health and the environment were not adequately documented or understood. Under this section of TSCA, the Administrator of the Environmental Protection Agency (EPA) is given the authority to require the development of adequate test data on the health and environmental effects of potentially hazardous chemicals. These data are taken into account by the Administrator in determining whether, and in what ways, to regulate or control potentially hazardous chemicals under other sections of TSCA or other statutes.

The primary purpose of this overview is to inform interested parties about 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 constraints affecting EPA's decision-making process; and selected key points and opportunities for public involvement in the section 4 process. This overview only presents a limited and fairly

*Much of the material contained in this Overview Package was developed by Schwartz and Connolly, Inc., Washington, D.C., under the supervision of the Test Rules Development Branch pursuant to EPA Contract No. 68-01-6527.

broad description of the Agency's decision-making process under section 4. More complete, detailed information on the process is provided in a separate information package entitled, "Guide to the TSCA Section 4 Process."

B. OBJECTIVES AND REQUIREMENTS OF SECTION 4

Section 4 of TSCA was designed to assure that: (1) those chemicals which may pose "unreasonable" risks of health or environmental damage receive priority attention for testing from EPA, (2) that EPA has the authority to require chemical manufacturers and processors to perform testing when it is needed to assess risk, and (3) that EPA does not require testing when such testing would not be useful or is not necessary. To these ends, the Act requires that EPA make three findings before requiring the manufacturers and processors of a chemical to test it for the potential effects of concern to the Agency.

Specifically, EPA must make all of the following findings with respect to the chemical:

(1) that the chemical may pose an "unreasonable risk" of harm to health or the environment; or that the chemical is produced in "substantial" quantities which may 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 manufacturing, processing, distribution, use, and disposal; and

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

In addition to making the above findings, EPA must consider the potential economic impacts of required testing before issuing such requirements under section 4.

If EPA makes all of the above findings with regard to a given chemical, EPA must assure that necessary testing is performed. This can be accomplished through the issuance of a rule requiring industry testing of the substance. Alternatively, if EPA can reach agreement with industry on a satisfactory testing program and testing schedule to be conducted by industry, then no test rule is needed.

EPA has found that industry testing conducted according to an agreed-upon program often offers several advantages. Because this approach tends to be less time consuming and more efficient than promulgating test rules, it offers all parties who participate in the section 4 process as well as the public the potential for saving resources. Moreover, such "negotiated" test programs may expedite the conduct of desired testing and, in turn, may lead to earlier resolution of

uncertainties for the public and for industry concerning a given chemical. If the test results indicate the need for control measures, such measures may be initiated more expeditiously than may be possible if testing is delayed until issuance of a test rule. Expediting the use of control measures results in improved protection of public health. Thus, EPA believes that, when testing is necessary, pursuit of a negotiated testing agreement with industry is an important option for implementing section 4 that should be explored.

EPA recognizes, however, that negotiations may not always be feasible or may not be completed successfully within the limited time period available.* In cases in which development of a negotiated program proves to be infeasible or proceeds at a pace that is unsatisfactory, the Agency will issue a proposed rule seeking to require that the necessary testing for the health and environmental effects of concern be performed.**

*The time period for publication of a notice which announces a negotiated testing agreement is one year in the case of a chemical "designated" by the Interagency Testing Committee for priority consideration by EPA. For further details, see discussion under part "C".

**The Agency may choose to issue an Advance Notice of Proposed Rulemaking (ANPR) rather than a Notice of Proposed Rulemaking (NPRM). This alternative is generally used when an ITC-designated chemical presents complicated issues on which the Agency seeks public comment early in the rulemaking process. The ANPR generally follows the same schedule as an NPR.

C. CONSTRAINTS UNDER WHICH EPA'S SECTION 4 PROCESS OPERATES

TSCA established a mechanism to assist EPA in determining which chemicals, if any, should be given priority attention under the testing provisions of the Act. Specifically, section 4(e) created the Interagency Testing Committee (ITC), composed of representatives of several federal agencies involved in regulation and research related to environmental and health issues. The function of the ITC is to review readily available data on a variety of chemicals and to recommend for EPA's priority consideration those substances which the ITC believes may require additional testing.

The Committee's recommendations to EPA are in the form of a list of chemical substances and mixtures known as the "Priority List". The ITC is required under section 4(e) to "designate" those recommendations on the list to which the EPA should respond within one year. If the ITC has designated a chemical for priority consideration, the law gives EPA only one year to independently perform a more comprehensive, in-depth analysis of available information on the chemical and either to initiate rulemaking to require testing of the chemical, or to publish its reasons for not doing so. This statutory one-year deadline has been reinforced by a court order compelling the Agency to meet the law's deadline.*

EPA's Test Rules Development Branch (TRDB) of the Office of Toxic Substances (OTS) is the EPA office with lead

*NRDC v. Costle, 14 ERC 1858 (S.D.N.Y., 1980).

responsibility for coordinating the Agency's section 4-related activities. During the one-year period after the ITC's designation of a chemical, OTS must analyze available information, obtain additional information, recommend a testing program if appropriate, obtain peer review of the testing program from other Agency offices and coordinate and respond to the Agency's and, in certain cases, the Office of Management and Budget's review of the testing program. For these reasons, OTS has established very tight deadlines for obtaining and evaluating relevant information, and for arriving at preliminary testing decisions for approval by upper-level Agency management.

In order to meet the statutory deadline, EPA's section 4 process has been carefully designed to include a series of interim deadlines and decision points. These interim steps help ensure both that the statutory one-year deadline will be met and that sufficient opportunity will be provided for public input as well as for the Agency's internal review of proposed testing decisions. For example, one critical milestone occurs approximately 14 weeks after EPA's receipt of the ITC's designations. At this time, a preliminary decision must be made by EPA staff as to whether, and for what effects, testing of a given chemical is needed. Thus, it is crucial that all data relevant to this "course-setting" decision be submitted to the Agency substantially earlier than the 14th week. Such data may include information regarding the production, use, exposure, environmental release, health effects, or environmental effects of a chemical.

Two other key points in the process are when EPA must decide whether to pursue negotiated testing or a test rule to obtain the necessary testing for a chemical. Week 25 in the process is the deadline by which a preliminary agreement must be reached between EPA and industry on an appropriate testing program if EPA is to decide to seek the necessary testing through a negotiated testing agreement in lieu of a test rule. Between weeks 31 and 33, EPA reviews industry's draft test program and decides whether a satisfactory negotiated agreement has been reached. If preliminary agreement has not been reached by week 25 or actual agreement by week 33 on a negotiated testing program, EPA will focus its resources on development and issuance of a proposed test rule. These deadlines are necessary to ensure that EPA can respond to ITC designations within the statutory one-year deadline.

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

D. KEY DECISION POINTS AND OPPORTUNITIES FOR PUBLIC INVOLVEMENT IN EPA's SECTION 4 PROCESS

This section presents information that is intended to assist interested parties in most effectively participating in EPA's section 4 process. Specifically, it outlines the points in the process both where the Agency's critical interim

decisions are made (decision points), and the times when comments on EPA's approach or its tentative decisions are solicited.* The interim decision points are highlighted by a double asterisk (**) because they represent deadlines by which interested parties must submit their views and relevant information in order for these to receive consideration prior to Agency decisions. A chart that identifies the major milestones in EPA's section 4 process is included at the end of this paper.

Week Number

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

EPA's receipt of the ITC's recommendations initiates the one-year period available for the Agency to respond to designated chemicals. Approximately two weeks after receipt of the ITC recommendations, EPA publishes a Federal Register, notice which:

- announces EPA's receipt of the ITC report;

*It should also be noted that the opportunity exists for public input during the ITC's consideration of chemicals for the Priority List, at the time a preliminary list of chemicals being considered by the ITC for addition to the Priority List is published in the Federal Register.

- o establishes a four-week period for submission of public comments on the ITC's recommendations (the first of several opportunities for public input); and
- o invites the public to attend Focus Meetings (see week 10 below) as well as subsequent public meetings (see week 16 below)*.

In addition, the submission of specific exposure and health and safety information on many of the ITC-designated chemicals is required by the TSCA sections 8(a) and 8(d) rules.

2-13 Public Submission of Relevant Information.

During these weeks prior to EPA's tentative decision on the need to require testing (see week 14 below), specific information is requested from all interested parties regarding the need for further testing and the types of tests, if any, which should be required for the chemical in question. These early weeks are the best time for the public to submit information relevant to EPA's testing decisions.

* The date and location of the Focus Meetings for each chemical are indicated in this notice. In addition, the notice states that parties interested in attending subsequent public meetings should contact EPA in order to be notified in advance of these meetings.

10 Public Focus Meeting.

A public meeting is held with representatives of the affected industry(s) and other interested parties for the purpose of exchanging information on the chemical. The meeting helps focus and narrow the Agency's inquiry and highlights the issues of greatest importance to EPA and to other interested parties. Usually, EPA makes further, more focused requests for data submissions from knowledgeable parties at this point, based upon the comments made. A summary of the focus meeting is placed in the public docket.

**14-15 Course-Setting Decision Made.

At this point, preliminary decisions are made by EPA about whether further testing of the chemical is warranted, and for what effects. These preliminary decisions are known as "course-setting." The information on which these decisions are based includes the ITC recommendations, public data submissions, information received during and after the public focus meeting, and the Agency's own preliminary evaluation of production, use, exposure, health and environmental data.

16 Public Meetings on Course-Setting.

EPA discusses the rationale and invites public comment on its preliminary decisions.

After consideration of public comments, EPA may determine that no testing is necessary. In this case, the Agency will publish a Federal Register notice at about week 38 which describes why EPA has determined that further testing is not required. If, on the other hand, EPA determines that testing is necessary, the Agency may seek testing under either a negotiated testing agreement or under a test rule. In such a case, EPA will welcome industry initiation of negotiations for the purpose of developing a negotiated testing program. In cases where test program negotiations are not feasible or are not progressing on schedule, EPA will pursue development of a rule to require testing of the chemical. (EPA may choose to pursue a test rule at any time during the negotiations.) The remainder of this outline applies only to the latter two possibilities (negotiated testing program or test rule).

**16-24 EPA/Industry Discussions; Opportunity for Separate Meetings with Interested Parties.

EPA may hold informal meetings with industry to attempt to reach an agreement regarding needed testing [a negotiated testing agreement]. The opportunity will also be provided, upon request, for

separate meetings with other interested parties who wish to present their views on testing needs and negotiation issues. Summaries of all meetings will be placed in the public docket after the negotiations are completed.

*24-25 Preliminary Agreement on Test Program.

EPA and industry must reach preliminary (conceptual) agreement on a testing program by this date. If no agreement is reached, EPA proceeds with preparation of a test rule proposal. EPA management considers whether negotiated testing is a viable option during week 25.

31 Draft Industry Test Program Submitted.

If preliminary agreement is reached at week 24, industry must submit to EPA its draft test program by week 31. This will need to include detailed testing protocols, explanations and/or justifications for the testing approach taken, descriptions of the decision-making process during the testing (including provisions for interaction with EPA) and provisions for release of test data.

**33 Negotiated Testing vs. Test Rule Development.

After review of industry's proposed test program, EPA decides whether it is likely that a satisfactory negotiated test agreement will be reached. If an agreement has not been reached which substantially addresses most of the testing details with only minor matters to clarify, EPA proceeds with preparation of a test rule proposal.

49 Publication of a Proposed Test Rule.

If a satisfactory negotiated test agreement cannot be reached, EPA publishes a proposed rule on which the public is invited to comment. (EPA also issues a proposed rule in the event that public comments on the proposed Negotiated Test Agreement notice raise significant issues about the adequacy of the proposed testing program and EPA and industry fail to resolve these issues. In this case, EPA is committed to issuing a proposed rule as soon as practicable.)

52 Publication in Federal Register of Proposed Negotiated Test Agreement Notice (NTA notice) and EPA's Decision Not to Initiate Rulemaking.

If a negotiated test agreement has been reached which appears to be satisfactory to EPA, a proposed

Negotiated Test Agreement notice is published in the Federal Register. This notice announces EPA's intent not to initiate rulemaking under section 4 of TSCA. The notice also requests public comment on industry's proposed test program during a 60-day period.

66 Final Industry Test Program Submitted.

In response to public comments on the proposed NTA notice and to any additional concerns raised by EPA, industry revises its proposed test program and submits the final negotiated test program. If the final program is significantly different from the proposed negotiated test program, a public meeting is held to discuss the final program.

83 Publication in the Federal Register of the Final Negotiated Test Agreement Notice.

If agreement is reached on a final negotiated test program, EPA publishes a final negotiated test agreement notice in the Federal Register noting its acceptance of the industry program in lieu of mandating testing by rule. The final test program is placed in the public record.

93 Publication in the Federal Register of the Final Test Rule.

If a proposed rule was published in the Federal Register (week 49), after consideration of public comments, EPA publishes a final test rule. This rule requires each manufacturer subject to the rule to submit within 60 days after publication of the rule either a letter of intent to perform the testing or an application for exemption (week 102). Test sponsors are required to submit study plans for the required tests within 120 days after publication of the rule (week 106).

127 Publication of Notice of Proposed Study Plans.

The study plans submitted by industry are proposed for comment in the Federal Register at approximately week 127.

158 Publication of Follow-Up Rule Adopting Final Test Standards.

After providing a 45-day comment period and an opportunity for a public meeting on the sponsors' proposed test study plans, EPA will adopt the study plans, as proposed or modified, as specific test standards for the test rule.

After EPA publishes a final negotiated test agreement notice (week 83) or a final rule adopting test standards for a test rule (week 158), industry is required to perform the testing according to the schedule specified in the agreement or rule. EPA will announce in the Federal Register the receipt and availability of data from testing performed under negotiated testing agreements and test rules.

E. FURTHER INFORMATION ON THE SECTION 4 PROCESS

For specific information on EPA's section 4 activities on particular chemicals and on the section 4 process, interested parties should contact the Test Rules Development Branch (TS-778), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460; (703-475-8130).

MILESTONES: SECTION 4 PROCESS

NOTIFICATION AND INFORMATION GATHERING, EXCHANGE AND ANALYSIS

Week	Event
0	Receive ITC Report
*2	Publish ITC Report & 8(a) & 8(d) Notices
6	Complete Preliminary Exposure Analysis
*10	Public Focus Meeting
14-15	Course-Setting Recommendations
*16	Public Meeting on Course-Setting Decision

Decision Not to Test vs. Test Decision

DECISION NOT TO TEST

19	Prepare DNT Notice
23-36	Agency Review
38	Publish in FR

TEST DECISION

16-23	Draft Support Documents
*16-24	EPA/Industry Discussions/Negotiations, Public Discussions
**24-25	Preliminary Agreement on Test Program

AGREEMENT ← → NO AGREEMENT

NEGOTIATED TESTING

26-31	EPA/Industry Test Negotiations
31	Industry Submits Draft Test Program
32	OTS Reviews Draft Test Program
**33	OTS Decision: Negotiated Testing vs. Rule → TEST RULE DEVELOPMENT
34-37	Prepare Proposed NTA Notice
38-50	Agency Review
*52	Publish in FR
52-61	Comment Period
62-64	OTS Reviews Comments/Discussions with Industry
66	Industry Submits Final Test Program
*67-68	OTS Reviews/Approves Final Test Program
66-69	Prepare Final NTA Notice
70-82	Agency Review
83	Publish in FR

TEST RULE DEVELOPMENT

26-31	Prepare Proposed Rule/ANPR
32-43	Agency Review
44-45	OMB Review
46-48	Administrator Signs
*49	Publish in FR
49-57	Comment Period
57-73	OTS Reviews Comments/ Prepares Final Test Rule
74-87	Agency Review
88-90	OMB Review
91-92	Administrator Signs
93	Publish in FR
102	Industry Submits Letters of Intent
106	Industry Submits Study Plans
*127	Propose Study Plans in FR
127-136	Comment Period
137-142	OTS Reviews Comments/Prepares Final Test Standards Rule
143-156	Agency Review
155-157	Administrator Signs
158	Publish in FR

DNT = Decision Not To Test NTA = Negotiated Test Agreement
FR = Federal Register ANPR = Advance Notice of Proposed Rulemaking
* Points in the process when public comment is solicited.
** Major decision points concerning negotiations versus test rules.