

40 CFR Part 773**[OPTS-47004D; TSH-FRL-2017-4a]****Dichloromethane, Nitrobenzene and 1,1,1-Trichloroethane Changes in Test Rules Policy****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule related notice.

SUMMARY: The decision, published elsewhere in the Proposed Rules section of this issue, to issue generic test methodology guidelines under the Toxic Substances Control Act instead of generic test methodology requirements and to establish test protocols on a case by case basis for test rules affects the proposed test rules on dichloromethane, nitrobenzene and 1,1,1-trichloroethane published in the Federal Register of June 5, 1981 (46 FR 30300). This notice announces that EPA is implementing these changes in policy and procedure for the dichloromethane, nitrobenzene, and 1,1,1-trichloroethane proposed test rules.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St. SW., Washington, D.C. 20460, toll free: (800-424-9065), in Washington, D.C. (554-1404), outside the USA: (Operator-554-1404).

SUPPLEMENTARY INFORMATION: In the Federal Register of June 5, 1981 (46 FR 30300), EPA issued proposed test rules for dichloromethane, nitrobenzene, and 1,1,1-trichloroethane under section 4 of TSCA. These rules would require manufacturers and processors of these chemicals to test them for certain health and environmental effects according to test standards prescribed by EPA. Among other things, the test standards prescribed by EPA in the proposed rules referenced the series of generic test methodology requirements that were then being developed by EPA for incorporation by citation into specific chemical test rules. Test methodology requirements for environmental effects were scheduled to be published prior to proposal of these test rules; however, publication was delayed. Because of this delay the comment period was extended from August 30, 1981, to November 30, 1981, as published in Federal Register of August 13, 1981 (46 FR 40898). The comment period was further extended to February 1, 1982, in the Federal Register of November 30, 1981 (46 FR 58108).

As noted elsewhere in today's Federal Register, since the proposal of these test rules the Agency has decided to change

the test standards policy. EPA will issue all generic TSCA test methodologies in the form of guidelines instead of generic test requirements. Second, sponsors of tests on individual substances will be required to prepare and submit their own protocols to EPA for review. This notice announces that EPA is implementing this change in policy for the dichloromethane, nitrobenzene, and 1,1,1-trichloroethane test rules and is adopting the following approach at this time.

The comments received in response to the June 5, 1981, proposal will be used in determining what health and environmental effects and characteristics of concern should be specified for testing in test rules for dichloromethane, nitrobenzene, and 1,1,1-trichloroethane. A final test rule will be issued specifying those effects and characteristics for these chemicals for which data are to be developed. Test sponsors will be required to submit test protocols to EPA within 90 days of the effective date of the final rules. A comment period and an opportunity for a public meeting will be provided at that time on the proposed protocols to be used in the development of data on the effects specified in the test rules for these three chemicals.

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

Dated: March 15, 1982.

Anne M. Gorsuch,
Administrator.

[FR Doc. 82-6135 Filed 3-25-82; 8:45 am]
BILLING CODE 6560-31-M

40 CFR Part 790**[OPTS-46009; TSH-FRL-2017-4b]****Change in Test Standards Policy and Test Rule Development Process****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule related notice.

SUMMARY: This notice explains that EPA is changing its approach for providing test standards for The Toxic Substances Control Act (TSCA) section 4 test rules. EPA will issue generic test methodology guidelines rather than generic test methodology requirements. Under the new policy, draft test protocols for individual test rules will be submitted by test sponsors, and the Agency will adopt final protocols after opportunity for public comment. The approach for providing Good Laboratory Practice (GLP) standards has not changed, although comments previously provided to the Agency will be taken into account prior to final adoption.

DATE: All comments on the protocol approval procedure should be submitted on or before May 10, 1982.

ADDRESS: Written comments should bear the document control number OPTS-46009 and should be submitted in triplicate to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-401, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St. SW., Washington, D.C. 20460, toll free: (800-424-9065), in Washington, D.C.: (554-1404), outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:**I. Background Concerning Test Standards**

Section 4 of the Toxic Substances Control Act (Pub. L. 94-469, 90 Stat. 2006; 15 U.S.C. 2603) authorizes the Administrator of the EPA to require manufacturers and processors of identified chemical substances and mixtures to test chemicals in accordance with applicable EPA test rules (sec. 4(a), (b)). TSCA specifies that each test rule must include standards for the development of test data. The test standards must prescribe the "health and environmental effects," and the "information relating to toxicity, persistence, and other characteristics which affect the health and environment for which test data are to be developed" (sections 4(b)(1) and 3(12)(A)). In addition, to the extent necessary to assure reliable and adequate data for such health and environmental effects, the Agency is authorized to prescribe the manner in which data are to be developed, any test methodology to be employed in the development of such data, and such other requirements as are necessary to provide such assurance (sections 4(b)(1)(B) and 3(12)(B)).

Pursuant to the above TSCA provisions the Agency previously proposed the following: Test Standards and GLP standards for health effects, published in the Federal Register of May 9, 1979 (44 FR 27334) and July 26, 1979 (44 FR 44054); Test Standards and GLP standards for physical, chemical, and persistence characteristics, and GLP standards for ecological effects, published in the Federal Register of November 21, 1980 (45 FR 77332).

These proposals contained detailed and fairly rigid generic requirements for test methodologies and laboratory

practices. Under its prior policy, the Agency intended to publish these as final requirements in the Federal Register after due consideration of public comments. (These requirements were previously referred to as generic "Test Standards;" this terminology has been changed to "generic requirements" to avoid confusion.) These generic requirements would have then been codified in the Code of Federal Regulations (CFR). Finally, these codified generic requirements would have been incorporated by citation into chemical-specific test rules as necessary. The generic requirements were to be accompanied by substantial supporting documentation which could also be cited in the chemical-specific rules. The test rule development process was designed to allow for appropriate modifications to be made in test methods if warranted by special characteristics of the substance to be tested.

II. Policy Change—Development of Test Methodologies on a Rule-by-Rule Basis

Various public comments took issue with the proposed approach to promulgating generic test methodology requirements. The commenters insisted that more flexibility in the selection of testing methods and in development of testing protocols was indicated because modifications of test requirements would be routinely necessary due to the dynamic nature of chemical testing.

EPA has reevaluated its approach to providing test standards and has determined that it will issue generic test methodology guidelines rather than generic test methodology requirements. The generic test methodology requirements previously proposed in the Federal Register will be revised as appropriate and published informally as test methodology guidelines.

The approach for providing GLP standards has not changed. Taking into consideration the comments previously received concerning GLPs, GLPs will be promulgated through a rulemaking procedure, codified in the CFR, and incorporated into section 4 test rules by citation. The Agency believes that enforceable GLPs are necessary to ensure reliable and adequate test data.

The Agency believes issuance of generic test methodology guidelines rather than generic test requirements will provide more flexibility for test facilities, test sponsors and the Agency itself to arrive at cost-effective, mutually agreeable test methodologies, and allow for the incorporation of scientific judgment where necessary. The Agency believes this approach will also allow for scientific innovation and encourage

the development of more sophisticated and scientifically advanced testing methodologies.

In light of this new policy, EPA is establishing a new procedure for the development of test rules. Under the new approach, test rule development will be a two phase process. The first phase will establish by rule that a chemical must be tested for certain effects and characteristics. The second phase will establish by rule the manner in which the testing is to be performed. The new procedure is described below. EPA requests comments on this procedure.

In phase I, following notice and comment, test rules will be promulgated for individual chemicals specifying the health and environmental effects and characteristics for which test data are to be developed, the GLP requirements, and the reporting requirements. In phase II, following promulgation of a test rule, sponsors will be required to develop test protocols for the development of data pertaining to the effects and characteristics specified in the test rule. Several documents, such as the TSCA, OECD, and FIFRA guidelines, will be referenced in the rules as guidance to test sponsors for test methodology development. The TSCA guidelines will be available from the National Technical Information Service (NTIS), Springfield, VA. Sponsors may select protocols listed in the referenced TSCA, OECD, and FIFRA guidelines, or may develop protocols of their own.

Sponsors will be required to submit their protocols to EPA within 90 days from the effective date of the rule. A 45-day comment period and an opportunity for a public meeting will be provided on the proposed protocols. If substantial new issues arise, EPA may allow a supplemental comment period. Following the close of the comment period, EPA will issue a rule adopting the protocols as proposed or modified. The approved and adopted protocols will become the enforceable test requirements for the test rules and will serve as the chemical specific test standards required by the Act (15 U.S.C. 2603(b)(1)).

The new protocol procedure would not require every person subject to the rule to submit a proposed test protocol. Section 4(b)(3) of TSCA permits joint sponsorship or designation of a third party to conduct testing and submit data, and section 4(c) permits exemptions from conducting tests and submitting data on a chemical substance if EPA determines that substance is equivalent to a substance for which data has been submitted or is being developed under section 4(a) and the

additional submission would be duplicative. EPA's proposed statement of exemption policy was published in the Federal Register of July 18, 1980 (45 FR 48524). The Agency is in the process of preparing a final statement of exemption policy which is compatible with this new procedure for developing test protocols.

Since the rules adopting the protocols would be enforceable requirements, modifications would require prior EPA approval except in emergency circumstances. An opportunity for public comment on substantive changes would be provided to the extent practicable. EPA requests comments on what procedures should be used for making modifications to rules with respect to test protocols.

The protocol development and approval procedure described above will provide greater flexibility than the previous test standards approach in establishing methodology requirements for test rules. As stated above, sponsors will be allowed to select protocols from a number of sources or to develop protocols of their own. There will now be the capability to require testing for effects of concern for which there are currently no available guidelines and allow test sponsors to use protocols which are in use in the scientific community. Sponsors would also be free to develop innovative testing methodologies. The provision for protocol approval allows EPA the capability to remedy deficiencies in sponsors' protocols to assure that data generated under test rules will be adequate and reliable.

Because this policy change affects the test rules proposed in the Federal Register of June 5, 1981 (46 FR 30300), a notice is published elsewhere in today's Federal Register explaining how this change will be accommodated for that proposal.

III. Compliance With Executive Order 12291

Under Executive Order 12291, EPA must judge whether an agency statement is "Major" and therefore, subject to the requirement of a Regulatory Impact Analysis. This policy statement is not Major because of the following reasons:

1. It will not have an annual effect on the economy of \$100 million or more.
2. It will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
3. It will not have a significant adverse effect on competition, employment, investment, productivity,

innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or foreign markets.

This notice was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E-107, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460.

Dated: March 15, 1982.

Anne M. Gorsuch,
Administrator.

[FR Doc. 82-6136 Filed 3-25-82; 8:45 am]

BILLING CODE 6560-31-M