enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: June 9, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a), and 371.

2. In § 180.516 the table to paragraph (a) is amended by adding alphabetically entries for the commodities ''flax seed'' and ''safflower seed''.

§ 180.516 Fludioxonil; tolerances for residues.

* * * * *

(a) * * *

Commodity	Parts per million
* * * * *	
Flax seed	0.05
* * * * *	
Safflower seed	0.01
* * * * *	

* * * * *

[FR Doc. 99–16685 Filed 6–29–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS–42193A; FRL–6067–4]

RIN 2070–AB94

Toxic Substances Control Act Test Guidelines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this rule, EPA is amending 7 of the 11 existing health effects guidelines. These guidelines are a part of the series of test guidelines which consist of standardized test procedures for test rules promulgated under section 4 of the Toxic Substances Control Act (TSCA), that are published in part 799 of Title 40 of the Code of Federal Regulations (CFR). These TSCA test guidelines are based on the harmonized test guidelines in the unified library for test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) for use in testing chemical substances to develop data for submission to EPA under TSCA, the Federal Food, Drug and Cosmetic Act (FFDCA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The process for developing and amending the harmonized test guidelines includes broad public participation and extensive involvement of the scientific community. The TSCA test guidelines do not in themselves impose any obligations on anyone until they are incorporated in a test rule promulgated under section 4 of TSCA.

DATES: This rule is effective on June 30, 1999.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Christine Augustyniak, Associate Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone numbers: (202) 554–1404 and TDD: (202) 554–0551; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Roger Nelson, Chemical Control Division, Office of Prevention, Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (202) 260–8163; e-mail address: nelson.roger@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be particularly interested in this action if you manufacture (defined by statute to include import) or process a chemical substance that could become the subject of a proposed test rule under TSCA section 4. This action does not, however, impose any obligations on anyone until the test guidelines are incorporated in a future test rule that would be proposed under TSCA section 4. Therefore, entities potentially affected by this action may include, but are not limited to:

Type of entity	SIC	NAICS	Examples of potentially affected entities
Chemical manufacturers or importers	28, 2911	325, 32411	Persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.
Chemical processors	28, 2911	325, 32411	Persons who process one or more of the subject chemical substances.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. The Standard Industrial Classification (SIC) codes and the North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document from and certain other available documents from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page, select ''Laws and Regulations'' and then look up the entry for this document under ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/EPA-TOX/1999/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–42193. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, Environmental Protection Agency, North East Rm. NE–B607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

3. *By phone*. If you need additional information about this action, you may also contact the person identify in the ''FOR FURTHER INFORMATION CONTACT'' section.

II. Background

A. What are Test Guidelines?

Test guidelines are a standardized set of test procedures or protocols organized by health effect or other testing endpoint. These guidelines present generally formulated procedures for laboratory testing of an effect or characteristic deemed important for the evaluation of health and environmental hazards of a chemical. These guidelines are designed to, when followed, produce data which are accurate, reliable, and reproducible. Such data are necessary for the regulatory programs under TSCA.

B. What are TSCA Test Guidelines?

TSCA test guidelines are guidelines which were established to meet the regulatory needs of TSCA, particularly the needs of the TSCA section 4 testing program. The TSCA section 4 testing program is a regulatory program which is based on the promulgation of rules requiring certain persons identified in the rule, usually manufacturers and processors of the chemical to conduct testing of the chemical specified in the rule. Section 4(b)(1)(B) of TSCA specifically requires that test rules promulgated under the section 4 include ''standards for the development of test data for such substance or mixture * * *.'' These ''standards for the development of test data'' specify how the study is to be conducted, what data will be collected, and how the data will be analyzed. Each test rule must specify such ''test standards'' which contain specifications for testing. Section 4(b)(1)

of TSCA describes the elements which must be described in these test standards.

The Agency has found that most of these elements can be standardized into the common set of protocols which EPA defines as ''test guidelines.'' These guidelines are organized by testing endpoint. The test rule itself can add or subtract to the requirements of the test guidelines in order to meet the unique testing circumstances for the particular chemical substance.

C. How are TSCA Test Guidelines Used?

The Agency uses this system of standardized guidelines, organized by testing endpoint and codified in a subpart in 40 CFR part 799 for use in cross-referencing in a TSCA section 4 action. When a section 4 test rule is promulgated, the test rule cross-references the appropriate TSCA test guideline for the bulk of the testing requirements. In this context, the public is given notice of, and an opportunity to comment on, these guidelines as they are applied in chemical-specific test rules. This approach eliminates the need to repeat the same test specifications for each substance-specific test rule since most of the specifications for testing do not change across substances. The test specifications in a guideline can be varied, when necessary, to the specific requirements of a test rule by amendatory language in the test rule itself.

D. Where Did the TSCA Test Guidelines Come From?

The TSCA test guidelines series were first promulgated in 1985 (50 FR 39252, September 27, 1985) and were established in 40 CFR parts 795, 796, 797, and 798. The Agency has over time amended and improved these guidelines (52 FR 19072, May 20, 1987) and in some cases revoked those guidelines which had not been cross-referenced in any test rules (60 FR 31917, June 19, 1995) (FRL–4955–2).

In 1991, EPA began an effort to blend the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) (and appeared in 40 CFR parts 795 through 798), the Office of Pesticides Programs (OPP) guidelines which appeared in publications of the National Technical Information Service (NTIS), and the guidelines published by the Organization for Economic Cooperation and Development (OECD). The product of this effort would be one set of guidelines which would be thus blended or ''harmonized.'' These harmonized guidelines would then be made available to the EPA, other government agencies, and the public through EPA's Internet web site and would be accessible by anyone with a personal computer and the ability to connect to the Internet. The EPA Internet web site would be the site and publication source for the ''OPPTS Harmonized Guidelines'' at http://www.epa.gov/epahome/research.htm/.

E. How Were These OPPTS Harmonized Test Guidelines Developed?

The OPPTS harmonized test guidelines were first drafted by EPA scientists for specific testing endpoints. These drafts were reviewed by other EPA experts and, in some instances, presented at domestic and international colloquia in order to solicit the views of recognized experts and the regulated community. These draft harmonized guidelines were made available on EPA's Internet web site as public drafts and public comment was solicited and received. After review of the public drafts and comments, EPA published the final OPPTS harmonized guidelines on EPA's Internet web site and announced their availability to the public in a **Federal Register** notice (63 FR 41845, August 5, 1998)(FRL–5740–1).

F. What is Done to Make TSCA Test Guidelines From the OPPTS Harmonized Test Guidelines?

Harmonization has resulted in significantly improved guidelines. However, creating a single set of guidelines which can be used by both OPP, in its administration of the FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA), and the Office of Pollution Prevention and Toxics, which administers TSCA presented certain challenges. Under FIFRA, test guidelines are used in an interactive process between the Agency and registrants seeking registration of pesticides or food residue tolerances. Flexibility to tailor required testing to individual circumstances is critical, and the Agency has considerable discretion to determine whether submitted test results are adequate to support the requested action. Under this scheme, registrants have an intrinsic motivation to conduct well-grounded testing. Thus, pesticide testing protocols tend to have few absolute requirements specifying the details of the conduct of the testing.

Under section 4 of TSCA, on the other hand, the Agency is required to impose prescriptive test requirements using notice and comment rulemaking. Rules promulgated under section 4 of TSCA must specify classes of affected parties and specify the standards to be followed by these parties in conducting the required testing. In contrast to FIFRA, the Agency does not interact with companies on an individual basis in designing the testing requirements.

TSCA section 4 rulemakings typically take years to complete. Without initiating another rulemaking process, the Agency has the ability to require further testing only if the tests were not conducted in accordance with the procedures specified in the test rule. In addition, the Agency has an alternative process of negotiating TSCA testing requirements via enforceable consent agreements (ECAs), but these agreements require the consent of all the parties involved. Under TSCA section 4 enforceable test standards, much in the conduct of these test protocols is left to the judgment of those professionals conducting the testing. EPA believes that certain provisions must be mandatory whenever the guidelines are cross-referenced in specific test rules.

Therefore, the Agency has used the OPPTS harmonized test guidelines developed using the public notice and comment process to create the TSCA-specific test guidelines which are the subject of this rule. TSCA section 4 test rules now cross-reference only the 40 CFR part 799 guidelines rather than the older, non-harmonized guidelines established in 40 CFR parts 795 through 798 mostly in 1985. The only significant difference between the TSCA test guidelines and the OPPTS harmonized test guidelines is that certain discretionary procedures in the OPPTS harmonized test guidelines are made mandatory (i.e., the guideline states that they ''must'' be carried out) in order to ensure the enforcibility of the test standard.

III. What Changes Is EPA Making to the TSCA Guidelines in 40 CFR Part 799?

EPA is making changes to seven of the existing 40 CFR part 799 guidelines in order that they more accurately reflect the equivalent OPPTS harmonized guideline as finalized in August 1998. The TSCA guidelines which were promulgated in August 1997 were based on early versions of the final OPPTS harmonized guidelines. Seven of the 11 TSCA guidelines promulgated in 1997 have differences in text with the OPPTS guidelines finalized in August 1998. This **Federal Register** document corrects those differences.

The changes that EPA is making to the existing 40 CFR part 799 guidelines are summarized in the following Table 1 and discussed guideline by guideline in detail below:

Table 1

Existing TSCA 40 CFR part 799 guideline and cite	Number of changes made to guideline in this rule
TSCA acute inhalation toxicity with histopathology (799.9135)	0
TSCA subchronic inhalation toxicity (799.9346)	8
TSCA prenatal developmental toxicity (799.9370)	0
TSCA reproduction and fertility effects (799.9380)	2
TSCA carcinogenicity (799.9420)	14
TSCA bacterial reverse mutation test (799.9510)	3
TSCA in vitro mammalian cell gene mutation test (799.9530)	0
TSCA mammalian bone marrow chromosomal aberration test (799.9538)	1
TSCA mammalian erythrocyte micronucleus test (799.9539)	2
TSCA neurotoxicity screening battery (799.9620)	1
TSCA immunotoxicity (799.9780)	0

The description of the changes with the detailed discussion of the changes being made to the existing 40 CFR part 799 TSCA guidelines are contained in the following lettered sections.

A. Section 799.9135 TSCA Acute Inhalation Toxicity with Histopathology

EPA is making no changes to this section.

B. Section 799.9346 TSCA Subchronic Inhalation Toxicity

1. EPA is revising the title of the TSCA guideline from ''TSCA Subchronic Inhalation Toxicity'' in § 799.9346 with ''TSCA 90-Day Inhalation Toxicity.'' This change tracks the change made in the title of the final OPPTS harmonized guideline.

2. EPA is revising paragraph (d) to track changes in the final OPPTS harmonized guideline. This revision better explains when a full study (using three test concentrations) might not be necessary.

3. EPA is revising the provision of paragraph (e)(1)(ii)(B) to track the OPPTS harmonized guideline emphasis that only testing on rodents (as opposed to all mammalian species) would be permitted. Provisions referencing non-rodents in the OPPTS guideline have been removed.

4. EPA is revising paragraph (e)(1)(iv)(A) be deleting provisions which imply the permissibility of using non-rodents as test animals. This language tracks the language in the final OPPTS harmonized guideline.

5. EPA is revising paragraphs (e)(1)(v)(E) and (e)(1)(v)(F) to track the language in the final OPPTS harmonized guideline. This language reorganizes these paragraphs and emphasizes the permissibility of using an unlimited supply of drinking water in the diets of the test animals.

6. EPA is revising the language in paragraph (e)(12) with new language which modifies the hematology and clinical chemistry parameters to track the modifications made in the final OPPTS harmonized guideline.

7. EPA is revising paragraph (e)(15)(i)(D) to delete the requirement for full histopathology of livers and kidneys of all animals. This change tracks the changes in the final OPPTS harmonized guideline.

8. EPA is adding additional requirements for test system information collection. New paragraphs (f)(3)(ii)(D)and (f)(3)(ii)(E) are added to include data on identification of the animal diet and the acclimation period. This tracks new language in the final OPPTS harmonized guideline.

C. Section 799.9370 TSCA Prenatal Developmental Toxicity

EPA made no changes to this section.

D. Section 799.9380 TSCA Reproduction and Fertility Effects

EPA is amending the existing TSCA Reproduction and Fertility Effects guideline by making several changes and clarifications to bring the text into agreement with the final OPPTS harmonized guideline 870.3800, Reproduction and Fertility Effects guideline (August 1998). Specific changes to the TSCA guideline are:

1. Paragraphs (e)(4)(i)(D) and (f)(3)(vi) were revised to incorporate the decisions made by the Agency in finalizing the OPPTS harmonized guideline to revise the definition of ''abnormal'' estrous cyclicity. There, the guideline wording which described assessment of cyclicity data in terms of normality was revised to indicate that the evaluation of the pattern of cycling to better reflect current scientific opinion.

2. Paragraph (e)(9) was revised to remove the triggers specified in the June 1996 draft guideline because EPA determined that these triggers would not be useful in identifying chemicals that require further examination. Instead, an assessment of F1 females for every study was specified (P females need not be assessed). Since EPA believes that there is more than one valid method of selecting the ovarian sections that will be evaluated and that the June 1996 draft guideline was excessively prescriptive in its description of methodology, specific instructions were removed in order to allow the performing laboratory to determine the most appropriate methodological criteria to attain biologically and statistically valid results. Supporting references were provided in § 799.9380 (g) of the TSCA guideline.

E. Section 799.9420 TSCA Carcinogenicity

EPA is amending the existing TSCA Carcinogenicity guideline by making several changes and clarifications to bring the text into agreement with the final OPPTS harmonized guideline 870.4200, Carcinogenicity guideline (August 1998). Specific changes to the TSCA guideline are:

1. EPA is further specifying its recommended procedures for test substance preparation. Paragraphs (d)(5)(ii)(C) and (d)(5)(ii)(D) are revised with modified language which is designed for consistency with other guidelines.

2. Paragraph (d)(5)(iii)(G) is revised to track technical changes made to the OPPTS harmonized guideline.

3. EPA is tracking changes made to the OPPTS harmonized guideline by adding provisions in paragraph (d)(7)(iv) recommending that water consumption be measured at the same intervals as the test substance if the test substance is administered in the drinking water.

4. EPA is tracking changes in the final OPPTS harmonized guideline by revising the provisions in paragraph (d)(9)(ii) for trimming and weighing organs during the gross necropsy phase

of the testing conducted under the TSCA guideline.

5. The requirement in paragraph (d)(9)(iii)(A)(*13*) for full histopathology and preservation of the bile duct (for rats when the rat is the test animal) is deleted in order to track changes made in the final OPPTS harmonized guideline.

6. The requirement in paragraph (d)(9)(iii)(D)(*5*) for full histopathology and preservation of the nose of the test animal has been deleted to track changes in the final OPPTS harmonized guideline.

7. The requirement in paragraph (d)(9)(iii)(E)(*6*) for full histopathology and preservation of the thymus of the test animal has been deleted to track changes in the final OPPTS harmonized guideline.

8. The requirement for the histopathology and the preservation of the female mammary gland was redesignated as new paragraph (d)(9)(iii)(F)(*8*). This addition tracks the change made in the final OPPTS harmonized guideline.

9. Requirements in paragraphs (d)(9)(iii)(G)(*1*), (d)(9)(iii)(G)(*2*), (d)(9)(iii)(G)(*4*), and (d)(9)(iii)(G)(*6*) for the histopathology and preservation of the lacrymal gland, skeletal muscle, the sternum, and femur were deleted in accordance with changes made in the final OPPTS harmonized guideline.

10. The requirement in paragraph (d)(10)(i)(D) for the full histopathology of lungs, liver and kidneys of all test animals was deleted in accordance with changes made in the final OPPTS harmonized guidelines.

11. Paragraph (d)(10)(ii) was revised to indicate the correct citation to the provisions specifying the methodology for examination of animals exposed to lower dose levels. This citation was incorrect in the original promulgation.

12. Paragraph (d)(10)(iv) was revised to remove the allowable maximum thickness provision for trimming tissues designated for microscopic examination. This change tracks changes made in the final OPPTS harmonized guideline.

13. New paragraphs (e)(3)(i)(B)(*4*) and (e)(3)(i)(B)(*5*) were added to specify that data on the identification of the animal diet and the animal acclimation period should be included in the test system data collection requirement. This addition tracks language added to the final OPPTS harmonized guideline.

14. A new paragraph (e)(4)(ii)(J) was added to specify that achieved dose (mg/kg/day) data (as a time-weighted average) would be recorded as part of the individual animal data recordation requirement if the test substance is administered in the diet or drinking water. A similar provision was added in the final OPPTS harmonized guideline.

F. Section 799.9510 TSCA Bacterial Reverse Mutation Test

1. Paragraph (e)(2)(i)(A)(*3*) was revised to delete language which indicated a preference for a particular approach to detect cross-linking mutagens. This revision tracks changes made in the final OPPTS harmonized guideline.

2. Paragraph (e)(2)(ii)(A) was revised to make grammatical corrections erroneously omitted in the original promulgation.

3. The language of paragraph (f)(3) was revised to be consistent with the test report requirement paragraph of the other TSCA guidelines.

G. Section 799.9530 TSCA In Vitro Mammalian Cell Gene Mutation Test

EPA is making no changes to this section.

H. Section 799.9538 TSCA Mammalian Bone Marrow Chromosomal Aberration Test

EPA is adding mandatory requirements in paragraph (e)(2)(ii)(B)(*3*) for the treatment of negative controls.

I. Section 799.9539 TSCA Mammalian Erythrocyte Micronucleus Test

The EPA is correcting some errors in the original promulgation.

1. Paragraphs (e)(2)(ii)(A) and (e)(3)(iii) were revised to be consistent with the comparable paragraphs in § 799.9538.

2. Paragraph (f)(2)(ii) was revised to identify the specific citation for the criteria to assess mutagencity instead of merely referring to ''the above criteria.''

3. The language of paragraph (f)(3) was revised to be consistent with the test report requirement paragraph of the other TSCA guidelines.

J. Section 799.9620 TSCA Neurotoxicity Screening Battery

The only change EPA is making to the TSCA neurotoxicity screening battery is the elimination of any need to use permanently injurious chemicals for behavioral measurements. Paragraph (e)(3)(ii) is thus revised by adding the same provisions which were added to the OPPTS final harmonized guideline.

K. Section 799.9780 TSCA Immunotoxicity

EPA is making no changes to this section.

IV. Why Is This Action Being Issued as a Final Rule?

EPA is publishing this action as a final rule without prior notice and an opportunity to comment because the Agency believes that providing notice and an opportunity to comment is unnecessary and would be contrary to the public interest. As explained above, this final rule does not impose any obligations on anyone until the test guidelines are incorporated in a test rule promulgated under TSCA section 4. Before any such test rule is promulgated, EPA will provide notice and an opportunity to comment on the incorporation of a particular test guideline into a specific test rule. In addition, the process for developing and amending the harmonized test guidelines includes broad public participation and extensive involvement of the scientific community. EPA therefore finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) to make this amendment without prior notice and comment. Thus, this rule may be promulgated without prior opportunity for public notice and comment, pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), and may be made effective immediately, without a 30-day delay, pursuant to 5 U.S.C. 553(d)(3).

V. How Do the Regulatory Assessment Requirements Apply to This Action?

This final rule does not impose any requirements. It only amends test guidelines in the TSCA series of test guidelines that are published in the CFR and which would be considered for potential incorporation in a future test rule that would be proposed under TSCA section 4. As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled Enhancing the Intergovernmental

Partnership (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). In addition, since this action is not subject to notice and comment requirements under the APA as discussed in Unit IV. of this preamble, or in any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

VI. Are There Any Applicable Voluntary Consensus Standards?

No. Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide an explanation to Congress, through OMB, when the Agency decides not to use available and applicable voluntary consensus standards when the NTTAA directs the Agency to do so.

As indicated earlier, this final rule does not impose any obligations on anyone until the test guidelines are incorporated in a test rule promulgated under TSCA section 4. Before any such test rule is promulgated, EPA will provide notice and an opportunity to comment on the incorporation of a particular test guideline into that specific test rule, including the availability of applicable voluntary consent standards.

In addition, although the NTTAA requirements do not specifically apply to the issuance of the harmonized test guidelines, EPA has sought comments on the availability of applicable voluntary consensus standards that should be considered during the development of future rules under TSCA. This allows the Agency to consider such standards during the development of the harmonized test guidelines, upon which the TSCA test guidelines are based.

VII. Will EPA Submit This Action to Congress and the Comptroller General?

Yes. The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). EPA has made such a good cause finding for this final rule, and established an effective date of June 30, 1999. Pursuant to 5 U.S.C. 808(2), this determination is supported by the brief statement in Unit IV. of this preamble. EPA will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Health, Reporting and recordkeeping requirements.

Dated: June 21, 1999.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.9346 is amended by revising the section heading, by revising paragraphs (d), (e)(1)(ii)(B), (e)(1)(iv)(A), (e)(1)(v)(E), (e)(1)(v)(F), (e)(12), and (e)(15)(i)(D), and adding paragraphs (f)(3)(ii)(D) and (f)(3)(ii)(E) to read as follows:

§ 799.9346 TSCA 90-Day Inhalation Toxicity.

* * * * *

(d) *Limit test.* If exposure at a concentration of 1 mg/L (expected human exposure may indicate the need for a higher concentration), or where this is not possible due to physical or chemical properties of the test substance, the maximum attainable concentration produces no observable toxic effects, then a full study using three concentrations might not be necessary.

(e) * * *

(1) * * *

(ii) * * *

(B) Dosing of rodents should generally begin no later than 8 weeks of age.

* * * * *

(iv) *Numbers.* (A) At least 20 animals (10 females and 10 males) should be used for each test group.

* * * * *

(v) * * *

(E) Control and test animals should be fed from the same batch and lot. The feed should be analyzed to assure adequacy of nutritional requirements of the species tested and for impurities that might influence the outcome of the rest. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water.

(F) The study should not be initiated until animals have been allowed a period of acclimatization/quarantine to environmental conditions, nor should animals from outside sources be placed on test without an adequate period of quarantine. An acclimatization period of at least 5 days is recommended.

* * * * *

(12) *Clinical pathology.* Hematology and clinical chemistry examinations shall be made on all animals, including controls, of each sex in each group. The hematology and clinical chemistry parameters should be examined at terminal sacrifice at the end of the study. Overnight fasting of the animals prior to blood sampling is recommended. Overall, there is a need for a flexible approach in the measures examined, depending on the observed or expected effects from a chemical, and in the frequency of measures, depending on the duration of potential chemical exposures.

(i) Hematology. The recommended parameters are red blood cell count, hemoglobin concentration, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration, white blood cell count, differential leukocyte count, platelet count, and a measure of clotting potential, such as prothrombin time or activated partial thromboplastin time.

(ii) Clinical chemistry. (A) Parameters which are considered appropriate to all studies are electrolyte balance, carbohydrate metabolism, and liver and kidney function. The selection of specific tests will be influenced by observations on the mode of action of the substance and signs of clinical toxicity.

(B) The recommended clinical chemistry determinations are potassium, sodium, glucose, total cholesterol, urea nitrogen, creatinine, total protein and albumin. More than 2 hepatic enzymes, (such as alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, sorbitol dehydrogenase, or gamma glutamyl transpeptidase) should also be measured. Measurements of addtional enzymes (of hepatic or other origin) and bile acids, may also be useful.

(C) If a test chemical has an effect on the hematopoietic system, reticulocyte counts and bone marrow cytology may be indicated.

(D) Other determinations that should be carried out if the test chemical is known or suspected of affecting related measures include calcium, phosphorus, fasting triglycerides, hormones, methemoglobin, and cholinesterases.

(iii) Optionally, the following urinalysis determinations could be performed during the last week of the study using timed urine volume collection: appearance, volume, osmolality or specific gravity, pH, protein, glucose, and blood/blood cells.

* * * * *

(15) * * *

(i) * * *

(D) Lungs of all animals. Special attention to examination of the respiratory tract should be made for evidence of infection as this provides a convenient assessment of the state of health of the animals

* * * * *

(f) * * *

(3) * * *

(ii) * * *

(D) Identification of animal diet.

(E) Acclimation period.

* * * * *

3. Section 799.9380 is amended by revising paragraphs (e)(4)(i)(D), (e)(9) and (f)(3)(vi) to read as follows:

§ 799.9380 TSCA reproduction and fertility effects.

* * * * *

(e) * * *

(4) * * *

(i) * * *

(D) Estrous cycle length and pattern should be evaluated by vaginal smears for all P and F1 females during a minimum of 3 weeks prior to mating and throughout cohabitation; care should be taken to prevent the induction of pseudopregnancy

* * * * *

(9) *Histopathology*—(i) *Parental animals.* Full histopathology of the organs listed in paragraph (e)(8)(i) of this section shall be performed for ten randomly chosen high dose and control P and F1 animals per sex, for those animals that were selected for mating. Organs demonstrating treatment-related changes shall also be examined for the remainder of the high-dose and control animals and for all parental animals in the low- and mid-dose groups. Additionally, reproductive organs of the low- and mid-dose animals suspected of reduced fertility, e.g., those that failed to mate, conceive, sire, or deliver healthy offspring, or for which estrous cyclicity or sperm number, motility, or morphology were affected, shall be subjected to histopathological evaluation. Besides gross lesions such as atrophy or tumors, testicular histopathological examination should be conducted in order to to identify treatment-related effects such as retained spermatids, missing germ cell layers or types, multinucleated giant cells, or sloughing of spermatogenic cells into the lumen. Examination of the intact epididymis should include the caput, corpus, and cauda, which can be accomplished by evaluation of a longitudinal section, and should be conducted in order to identify such lesions as sperm granulomas, leukocytic infiltration (inflammation), aberrant cell types within the lumen, or the absence of clear cells in the cauda epididymal epithelium. The postlactational ovary should contain primordial and growing follicles as well as the large corpora lutea of lactation. Histopathological examination should detect qualitative depletion of the primordial follicle population. A quantitative evaluation of primordial follicles should be conducted for all F1 females; the number of animals, ovarian section selection, and section sample size should be statistically appropriate for the evaluation procedure used. Examination should include enumeration of the number of primordial follicles, which can be combined with small growing follicles (see paragraphs (g)(1) and (g)(2) of this section), for comparison of treated and control ovaries.

(ii) *Weanling.* For F1 and F2 weanlings, histopathological examination of treatment-related abnormalities noted in macroscopic examination should be considered, if such evaluation were deemed appropriate and would contribute to the interpretation of the study data.

(f) * * *

(3) * * *

(vi) Number of P and F1 females cycling pattern and mean estrous cycle length.

* * * * *

4. Section 799.9420 is amended as follows:

a. By revising paragraphs (d)(5)(ii)(C), (d)(5)(ii)(D), (d)(5)(iii)(G), (d)(7)(iv), (d)(9)(ii), (d)(9)(iii)(D)(*5*), (d)(10)(ii), and (d)(10)(iv).

b. By adding paragraphs (d)(9)(iii)(F)(*8*), (e)(3)(i)(B)(*4*), (e)(3)(i)(B)(*5*), and (e)(4)(ii)(J).

c. By removing paragraphs (d)(9)(iii)(A)(*13*), (d)(9)(iii)(E)(*6*), (d)(9)(iii)(G)(*1*), (d)(9)(iii)(G)(*2*), (d)(9)(iii)(G)(*4*), and (d)(9)(iii)(G)(*6*) and redesignating paragraph (d)(9)(iii)(G)(*3*) as paragraph (d)(9)(iii)(G)(*1*) and paragraph (d)(9)(iii)(G)(*5*) as paragraph (d)(9)(iii)(G)(*2*), and removing paragraph (d)(10)(i)(D).

§ 799.9420 TSCA carcinogenicity.

* * * * *

(d) * * *

(5) * * *

(ii) * * *

(C) Preparation of test substance. Liquid test substances are generally used undiluted, except as indicated in paragraph (e)(4)(vi) of this section. Solids should be pulverized when possible. The substance should be moistened sufficiently with water or, when necessary, with a suitable vehicle to ensure good contact with the skin. When a vehicle is used, the influence of the vehicle on toxicity of, and penetration of the skin by, the test substance should be taken into account. The volume of application should be kept constant, e.g. less than 100 uL for the mouse and less than 300 uL for the rat. Different concentrations of test solution should be prepared for different dose levels.

(D) The test substance shall be applied uniformly over a shaved area which is approximately 10 percent of the total body surface area. In order to dose approximately 10 percent of the body surface, the area starting at the scapulae (shoulders) to the wing of the ileum (hipbone) and half way down the flank on each side of the animal should be shaved. With highly toxic substances, the surface area covered may be less, but as much of the area as possible should be covered with as thin and uniform a film as practical.

(iii) * * *

(G) The actual concentration of the test substance shall be measured in the breathing zone. During the exposure period, the actual concentrations of the test substance should be held as constant as practicable, monitored continuously or intermittently depending on the method of analysis. Chamber concentrations may be measured using gravimetric or analytical methods as appropriate. If

trial run measurements are reasonably consistent (plus or minus 10 percent for liquid aerosol, gas, or vapor; plus or minus 20 percent for dry aerosol), the two measurements should be sufficient. If measurements are not consistent, then three to four measurements should be taken.

* * * * *

(7) * * *

(iv) Measurements of feed consumption should be determined weekly during the first 13 weeks of the study and at approximately monthly intervals thereafter unless health status or body weight changes dictate otherwise. Measurement of water consumption should be determined at the same intervals if the test substance is administered in the drinking water.

* * * * *

(9) * * *

(ii) At least the liver, kidneys, adrenals, testes, epididymides, ovaries, uterus, spleen, brain, and heart should be weighed wet as soon as possible after dissection to avoid drying. The lungs should be weighed if the test substance is administered by the inhalation route. The organs should be weighed from interim sacrifice animals as well as from at least 10 animals per sex per group at terminal sacrifice.

(iii) * * *

(D) * * *

(*5*) Nose.

* * * * *

(F) * * *

(*8*) Female mammary gland.

* * * * *

(10) * * *

(ii) If the results show substantial alteration of the animal's normal life span, the induction of effects that might affect a neoplastic response, or other effects that might compromise the significance of the data, the next lower dose levels shall be examined as described in paragraph (d)(10)(i) of this section.

* * * * *

(iv) Tissues and organs designated for microscopic examination should be fixed in 10 percent buffered formalin or a recognized suitable fixative as soon as necropsy is performed and no less than 48 hours prior to trimming.

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(e) * * *

(3) * * *

(i) * * *

(B) * * *

(*4*) Identification of animal diet.

(*5*) Acclimation period.

* * * * *

(4) * * *

(ii) * * *

(J) Achieved dose (mg/kg/day) as a time-weighted average if the test substance is administered in the diet or drinking water.

5. Section 799.9510 is amended by revising paragraphs (e)(2)(i)(A)(*3*) introductory text, (e)(2)(ii)(A), and (f)(3) introductory text to read as follows:

§ 799.9510 TSCA bacterial reverse mutation test.

* * * * *

(e) * * *

(2) * * *

(i) * * *

(A) * * *

(*3*) At least five strains of bacteria should be used. These should include four strains of S. typhimurium (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four S. typhimurium strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidizing mutagens, cross-linking agents, and hydrazines. Such substances may be detected by E. coli WP2 strains or S. typhimurium TA102 (see reference in paragraph (g)(19) of this section) which have an AT base pair at the primary reversion site. Therefore the recommended combination of strains is:

* * * * *

(ii) * * *

(A) *Solvent/vehicle.* The solvent/vehicle should not be suspected of chemical reaction with the test substance and shall be compatible with the survival of the bacteria and the S9 activity (for further information see the reference in paragraph (g)(22) of this section). If other than well-known solvent/vehicles are used, their inclusion should be supported by data indicating their compatibility. It is recommended that wherever possible, the use of an aqueous solvent/vehicle be considered first. When testing water-unstable substances, the organic solvents used be free of water.

* * * * *

(f) * * *

(3) *Test report.* The test report shall include the following information:

* * * * *

6. Section 799.9538 is amended by revising paragraph (e)(2)(ii)(B)(*3*) to read as follows:

§ 799.9538 TSCA mammalian bone marrow chromosomal aberration test.

* * * * *

(e) * * *

(2) * * *

(ii) * * *

(B) * * *

(*3*) Negative controls, treated with solvent or vehicle alone, and otherwise treated in the same way as the treatment groups, shall be included for every sampling time, unless acceptable inter-animal variability and frequencies of cells with chromosome aberrations are available from historical control data. If single sampling is applied for negative controls, the most appropriate time is the first sampling time. In the absence of historical or published control data demonstrating that no deleterious or mutagenic effects are induced by the chosen solvent/vehicle, untreated animals should be used.

* * * * *

7. Section 799.9539 is amended by revising paragraphs (e)(2)(ii)(A), (e)(3)(iii), (f)(2)(ii), and (f)(3) introductory text to read as follows:

§ 799.9539 TSCA mammalian erythrocyte micronucleus test.

* * * * *

(e) * * *

(2) * * *

(ii) * * *

(A) *Solvent/vehicle.* The solvent/vehicle shall not produce toxic effects at the dose levels used, and shall not be suspected of chemical reaction with the test substance. If other than well-known solvents/vehicles are used, their inclusion should be supported with reference data indicating their compatibility. It is recommended that wherever possible, the use of an aqueous solvent/vehicle should be considered first.

* * * * *

(3) * * *

(iii) *Dose levels.* If a range finding study is performed because there are no suitable data available, it shall be performed in the same laboratory, using the same species, strain, sex, and treatment regimen to be used in the main study (guidance on dose setting is provided in the reference in paragraph (g)(9) of this section). If there is toxicity, three dose levels shall be used for the first sampling time. These dose levels shall cover a range from the maximum to little or no toxicity. At the later sampling time only the highest dose needs to be used. The highest dose is defined as the dose producing signs of toxicity such that higher dose levels, based on the same dosing regimen, would be expected to produce lethality. Substances with specific biological activities at low non-toxic doses (such as hormones and mitogens) may be exceptions to the dose-setting criteria and should be evaluated on a case-by-case basis. The highest dose may also be defined as a dose that produces some indication of toxicity in the bone marrow (e.g. a reduction in the proportion of immature erythrocytes

among total erythrocytes in the bone marrow or peripheral blood).

* * * * *

(f) * * *

(2) * * *

(ii) A test substance for which the results do not meet the criteria in paragraph (f)(2)(i) of this section is considered non-mutagenic in this test.

* * * * *

(3) *Test report.* The test report shall include the following information:

* * * * *

8. Section 799.9620 is amended by revising paragraph (e)(3)(ii) to read as follows:

§ 799.9620 TSCA neurotoxicity screening battery.

* * * * *

(e) * * *

(3) * * *

(ii) Positive control data from the laboratory performing the testing shall provide evidence of the ability of the observational methods used to detect major neurotoxic endpoints including limb weakness or paralysis, tremor, and autonomic signs. Positive control data are also required to demonstrate the sensitivity and reliability of the activity-measuring device and testing procedures. These data should demonstrate the ability to detect chemically induced increases and decreases in activity. Positive control groups exhibiting central nervous system pathology and peripheral nervous system pathology are also required. Separate groups for peripheral and central neuropathology are acceptable (e.g. acrylamide and trimethyl tin). Permanently injurious substances need not be used for the behavioral tests. Historical data may be used if the essential aspects of the experimental procedure remain the same. Periodic updating of positive control data is recommended. New positive control data should also be collected when personnel or some other critical element in the testing laboratory has changed.

* * * * *

[FR Doc. 99–16526 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF COMMERCE

48 CFR Part 1352

[Docket No. 981202294–8294–01]

RIN 0605–AA13

Solicitation Provisions and Contract Clauses; Women-Owned Small Business Sources

AGENCY: Department of Commerce.

ACTION: Final rule.

SUMMARY: The Department of Commerce (Department) is removing a section of the Commerce Acquisition Regulation (CAR) pertaining to the Federal Acquisition Regulation (FAR) contract clause ''Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan.'' The FAR contains requirements for where the clause ''Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan'' is required in solicitations and contracts. Since the CAR is intended to supplement and implement the FAR without paraphrasing or duplicating the FAR language, the Department is removing the section of the CAR which duplicates the FAR requirement.

EFFECTIVE DATE: This rule is effective July 30, 1999.

FOR FURTHER INFORMATION CONTACT: Ms. Lisa Jandovitz, 202–482–0202.

SUPPLEMENTARY INFORMATION: The Federal Acquisition Regulations System was established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies. The Federal Acquisition Regulations System consists of the Federal Acquisition Regulation (FAR), which is the primary document, and agency acquisition regulations that implement the FAR. The Commerce Acquisition Regulation (CAR) is codified at 48 CFR chapter 13. The solicitation provisions and contract clauses are codified at 48 CFR part 1352. The CAR is intended to supplement and implement the FAR without paraphrasing or duplicating FAR language. Therefore, section 1352.219–1 of Title 48 is being removed because it duplicates the FAR clause in 48 CFR 52–219–9 as prescribed by 48 CFR 19.708(b). There is no change in the solicitation provisions and contract clauses that will be used by the Department.

Rulemaking Requirements

This rule was determined to be ''not significant'' for purposes of Executive Order 12866. This rule does not contain a collection of information for purposes of the Paperwork Reduction Act. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612. The Department finds good cause to issue this rule without notice of proposal rulemaking and the opportunity for public participation. These procedures are unnecessary for this technical amendment to remove duplicate language that is codified in the Federal Acquisition Regulation (FAR). Retaining the present language could be confusing to the public. The rule will have no effect on procurement policy or cost or administrative impact on contractors or offerors. Because a notice of proposed rulemaking is not required by the Administrative Procedure Act (5 U.S.C. 553) or any other law for this rule, the analytical requirements of the Regulatory Flexibility Act are not applicable.

List of Subject in 48 CFR Part 1352

Government contracts, Government procurement.

For the reasons set forth in the preamble, 48 CFR part 1352 is amended to read as follows:

PART 1352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

1. The authority citation is revised to read as follows:

Authority: 41 U.S.C. 418b.

1352.219–1 [Removed]

2. Remove section 1352.219–1.

Dated: June 21, 1999.

Christine Makris,

Director, Acquisition Policy and Programs.

[FR Doc. 99–16579 Filed 6–29–99; 8:45 am]

BILLING CODE 3510–EC–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 990304062–9062–01; I.D. 062399A]

Fisheries of the Economic Exclusive Zone Off Alaska; Shallow-water Species Fishery by Vessels using Trawl Gear in the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.