

issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1991 (46 FR 24950).

**List of Subjects in 40 CFR Part 180**

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 1992.

Douglas D. Camp,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

**PART 180—(AMENDED)**

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.1001, paragraph (d) is amended in the table therein by adding and alphabetically inserting the following inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirements of a tolerance.

(d) \* \* \*

Inert ingredients	Limits	Uses
N,N-Bis 2-(omega-hydroxy poly oxyethylene/poly oxypropylene ethyl alkylamine; the reaction product of 1 mole of N,N-bis(2-hydroxyethyl) alkylamine and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C <sub>8</sub> -C <sub>18</sub> ) is derived from coconut, cottonseed, soya, or tallow acids	Not more than 0.5% of pesticide formulation	Surfactant.

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**40 CFR Parts 766 and 799**

[OPPTS-40023; FRL 4045-9]

**Technical Amendments to Test Rules and Consent Orders**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** Pursuant to 40 CFR 790.55 and 790.68, EPA has approved by letter certain modifications to test standards and schedules for chemical testing programs under section 4 of the Toxic Substances Control Act (TSCA). These modifications, requested by test sponsors, will be incorporated and codified in the respective test regulation or consent order. Because these modifications do not significantly alter

the scope of a test or significantly change the schedule for its completion, EPA approved these requests without seeking notice and comment. EPA will annually publish a notice describing all of the modifications granted by letter for the previous year.

**EFFECTIVE DATE:** June 12, 1992.

**FOR FURTHER INFORMATION CONTACT:** Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

**SUPPLEMENTARY INFORMATION:** EPA issued an interim final rule published in the Federal Register of September 1, 1989 (54 FR 36311), amending procedures for modifying test standards and schedules for test rules and testing consent orders under section 4 of TSCA. The amended procedures allow EPA to approve requested modifications which do not alter the scope of a test or significantly change the schedule for its

completion. These modifications are approved by letter without public comment. The rule also requires immediate placement of these letters in EPA's public files and publication of these modifications in the Federal Register. This document includes modifications approved from January 1, 1991, through December 31, 1991. For a detailed description of the rationale for these modifications, refer to the submitters' letters and EPA's responses in the public record for this rulemaking.

**I. Discussion of Modifications**

Each chemical discussed in this rule is identified by a specific CAS number and docket number. Copies of correspondence relating to specific chemical modifications may be found in docket number (OPPTS-40023) or the chemical-specific docket established for this rule. The following table lists all chemical-specific modifications approved from January 1, 1991, through December 31, 1991:

**MODIFICATIONS TO TEST STANDARDS AND CONSENT ORDERS JANUARY 1, 1991 THROUGH DECEMBER 31, 1991**

Chemical/CAS Number	40 CFR Cite	Required Test	Modifications	Docket No.
Final Rule Chemicals alkyl ether of tetrabromobisphenol-A (25327-89-3)	766.35	Analytical testing	5	40023/83002L

## MODIFICATIONS TO TEST STANDARDS AND CONSENT ORDERS JANUARY 1, 1991 THROUGH DECEMBER 31, 1991—Continued

Chemical/CAS Number	40 CFR Cite	Required Test	Modifications	Docket No.
tetrabromobisphenol-A-bisethoxylate (4162-45-2)	766.35	Analytical testing	5,8	40023/83002L
3,4',5-tribromosalicylanilide (87-10-5)	766.35	Analytical testing	8	40023/83002L
tetrabromobisphenol-A (79-84-7)	766.35	Analytical testing	5	40023/83002L
2,4,6-tribromophenol (118-79-6)	766.35	Analytical testing	5	40023/83002L
decabromodiphenyl oxide (1163-18-5)	766.35	Analytical testing	5	40023/83002L
pentabromodiphenyl oxide (32534-81-8)	766.35	Analytical testing	5	40023/83002L
octabromodiphenyl oxide (32536-52-0)	766.35	Analytical testing	5	40023/83002L
1,2-bis(tri-bromophenoxy)ethane (37853-59-1)	766.35	Analytical testing	5	40023/83002L
2,3,5,6-tetrachloro-2,5-cyclohexadiene-1,4-dione (118-75-2)	766.35	Analytical testing	5	40023/83002L
1,2,4-trichlorobenzene (120-82-1)	799.1053	oncogenicity study	5	40023/47002J
fluoroalkenes, vinyl fluoride (75-02-5)	799.1700	oncogenicity test in rats	9	40023/42002M
commercial hexane (110-54-3), (96-37-7)	799.2155	pharmacokinetics	5	40023/42084K
tributyl phosphate (126-73-8)	799.4360	daphnid chronic toxicity test, fish early-life stage test, oral/dermal pharmacokinetics test	5	40023/42100D
unsubstituted phenylenediamines (95-54-5 and 106-50-3)	799.3300	chronic Daphnia testing with <i>o</i> -pda and <i>p</i> -pda	5	40023/42008I
<b>Consent Orders</b>				
C.I. disperse blue 79:1 (3618-72-2)	799.5000	rainbow trout early life cycle test	5	40023/42103C
crotonaldehyde (4170-30-3)	799.5000	fish early life stage testing (fathead minnow), daphnid chronic toxicity testing	5	40023/42108A
disodecyl phenyl phosphite (25550-86-6)	799.5000	subchronic delayed neurotoxicity study of organophosphorus substances, neurotoxic esterase assay	5	40023/42101C
4-nonylphenol, branched (84852-15-3)	799.5000	fathead minnow test, tadpole bioassay, midge bioassay	5	40023/42104D
octamethylcyclotetrasiloxane (556-87-2)	799.5000	bioconcentration test, biodegradation test, bioaccumulation test, sediment/invertebrate studies	5,8	40023/42071D
1,1,1-trichloroethane (71-55-6)	799.5000	dose levels and dose selection, delayed matching-to-position test, breeding, duration of dosing	7	40023/42058F
triethylene glycol monomethyl ether (112-35-6)	799.5000	Analytical testing	8	40023/42080H

**MODIFICATIONS**

1. Modify sampling schedule.
2. Change to test substance (form/purity).
3. Change in non-critical test procedure or condition.
4. Add satellite group for further testing.
5. Extend test or protocol deadline, delete test initiation date.
6. Clarify and/or add specific guideline requirement.
7. Alternate specific guideline requirement approved for certain test(s).
8. CAS No. correction.
9. Test standard amendment

**II. Public Record**

EPA has established a public record for this rulemaking (docket number OPPTS-40023). The record includes the information considered by EPA in evaluating the requested modifications.

The record is available for inspection from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays, in rm. G-004, NE Mall, 401 M St., SW., Washington, DC 20460.

**III. Other Regulatory Requirements****A. Executive Order 12291**

Under Executive Order 12291, EPA must judge whether a rule is "major"

and therefore subject to the requirement of a Regulatory Impact Analysis. This rule, listing modifications of test standards and schedules for tests required under test rules and testing consent agreements under the authority of section 4 of TSCA, is not major because it does not meet any of the criteria set forth in section 1(b) of the Order.

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

**B. Regulatory Flexibility Act**

Under the Regulatory Flexibility Act, (5 U.S.C. 601 et seq.), EPA is certifying that this rule will not have a significant impact on a substantial number of small businesses because the modifications listed in this rule have been made to expedite the development of test data and to reduce certain paperwork burdens associated with current regulations.

**C. Paperwork Reduction Act**

The information collection requirements associated with this rule have been approved by OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and have been assigned OMB control number 2070-0033.

EPA has determined that this rule does not change existing recordkeeping or reporting requirements nor does it impose any additional recordkeeping or reporting requirements on the public.

Send comments regarding this rule including suggestions for reducing this burden to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0033) Washington, DC 20503.

**List of Subjects in 40 CFR Parts 766 and 799**

Chemicals, Chemical export, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, Testing.

Dated: May 29, 1992.

Mark A. Greenwood,  
Director, Office of Pollution Prevention and  
Toxics.

Therefore, 40 CFR parts 766 and 799  
are amended as follows:

1. In part 766:

**PART 766—[AMENDED]**

a. The authority citation for part 766  
continues to read as follows:

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

b. In § 766.35, by revising paragraphs  
and (a)(2)(ii)(A), (b)(4)(i) and (f) to read  
as follows:

**§ 766.35 Dibenzo-para-dioxins/  
dibenzofurans.**

- (a) \* \* \*
- (2) \* \* \*
- (ii) \* \* \*

(A) Except as noted for the submitter  
and substance specified in the following  
table, protocols for testing must be  
submitted 24 months after manufacture  
or importation begins for chlorinated  
chemical substances.

CAS No.	Submitter	Chemical	Due Date
118-75-2	Rhone Poulenc	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione	June 19, 1992

(b) \* \* \*  
(4) Test results. (i) Test results must  
be submitted to EPA not later than 270

days after EPA's transmission of  
comments or 180 days after a final  
protocol is submitted to EPA, whichever  
is shorter, except as noted for the

submitters and substances specified in  
the following table:

CAS No.	Submitter	Chemical	Due Date
79-84-7	Great Lakes	Tetrabromobisphenol-A	May 26, 1992
79-84-7	Ethyl	Tetrabromobisphenol-A	May 26, 1992
79-84-7	Ameribrom	Tetrabromobisphenol-A	May 26, 1992
87-10-5	Pfister	3,4'-5-tribromosalicylanilide	45 days after protocol approval
118-79-6	Great Lakes	2,4,6-Tribromophenol	May 26, 1992
1163-19-5	Ameribrom	Decabromodiphenyloxide	May 26, 1992
1163-19-5	Ethyl	Decabromodiphenyloxide	May 26, 1992
1163-19-5	Great Lakes	Decabromodiphenyloxide	May 26, 1992
4162-45-2	Great Lakes	Tetrabromobisphenol-A-bisethoxyate	May 26, 1992
25327-89-3	Great Lakes	Allyl Ether of Tetrabromobisphenol-A	May 26, 1992
32534-81-9	Great Lakes	Pentabromodiphenyloxide	May 26, 1992
32534-81-9	Ameribrom	Pentabromodiphenyloxide	May 26, 1992
32536-52-0	Ameribrom	Octabromodiphenyloxide	May 26, 1992
32536-52-0	Ethyl	Octabromodiphenyloxide	May 26, 1992
32536-52-0	Great Lakes	Octabromodiphenyloxide	May 26, 1992
37853-59-1	Great Lakes	1,2-bis(tribromophenoxy)ethane	90 days after protocol approval

(f) Effective date. (1) The effective  
date of this final rule is July 6, 1987,  
except for paragraphs (a)(2)(i)(B),  
(a)(2)(ii)(A), and (b)(4)(i) of this section.

(2) The effective date for paragraph  
(a)(2)(i)(B) is May 21, 1991. The effective  
date for paragraphs (a)(2)(ii)(A), and  
(b)(4)(i) is June 12, 1992.

(3) The guidelines and other test  
methods cited in this rule are referenced  
as they exist on the effective date of the  
final rule.

2. In part 799:

**PART 799—[AMENDED]**

a. The authority citation for part 799  
continues to read as follows:  
Authority: 15 U.S.C. 2603, 2611, 2625.

b. In § 799.1053, by revising  
paragraphs (e)(1)(ii)(A) and (g) and by  
adding and revising paragraph (e)(2) to  
read as follows:

**§ 799.1053 Trichlorobenzenes.**

(e) \* \* \*

(1) \* \* \*  
(ii) Reporting requirements. (A) The  
oncogenicity test shall be completed and  
the final results submitted to EPA by  
June 30, 1994.

(2) [Reserved]

(g) Effective date. (1) The effective  
date of the final phase II rule is August  
14, 1987, except for paragraphs  
(d)(4)(iii)(A) and (e)(1)(ii)(A) of this  
section. The effective date for paragraph  
(d)(4)(iii)(A) of this section is March 1,  
1990. The effective date for paragraph  
(e)(1)(ii)(A) of this section is [insert date  
of publication in the Federal Register].

(2) The guidelines and other test  
methods cited in this rule are referenced  
as they exist on the effective date of the  
final rule.

c. In § 799.1700 by adding paragraph  
(c)(4)(i)(A)(2)(ii) and removing and  
reserving paragraph (c)(4)(i)(C) and by  
revising paragraph (d) to read as  
follows:

**§ 799.1700 Fluoroalkenes.**

- (c) \* \* \*
- (4) \* \* \*
- (i) \* \* \*
- (A) \* \* \*
- (2) \* \* \*

(ii) All rats of test groups in which  
survival is approximately 25 percent of  
rats at risk (approximately 25 percent of  
60, or approximately 15 rats) will be  
sacrificed near the time that 25 percent  
survival is achieved. All rats surviving  
the 24-month test period will be  
sacrificed and necropsied. The order of  
sacrifice for rats at all pathological  
evaluations will be random among all  
exposure groups within a sex. Moribund  
animals should be removed and  
sacrificed when noticed.

(C) [Reserved]

(d) Effective date. (1) The effective  
date of the final rule is July 22, 1987,  
except for paragraphs (c)(1)(i)(C)(1),  
(c)(1)(ii)(A), and (c)(4)(i) of this section.

(2) The effective date of paragraphs (c)(1)(i)(C)(1) and (c)(1)(ii)(A) is May 21, 1990. The effective date for paragraphs (c)(4)(i)(A)(1), (c)(4)(i)(A)(2)(1), (c)(4)(i)(B), and (c)(4)(i)(D) is May 21, 1991. The effective date of paragraphs (c)(4)(i)(A)(2)(ii) and (c)(4)(i)(C) is June 12, 1992.

(3) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

d. In § 799.2155 by revising paragraphs (c)(8)(i), (c)(8)(ii)(A) and (d) read as follows:

**§ 799.2155 Commercial hexane.**

- (c) . . . .
- (8) . . . .

(i) **Required testing.** (A)

Pharmacokinetics testing shall be conducted in rats in accordance with § 795.232 of this chapter, except for paragraph (c)(1)(ii) of § 795.232.

(B) For the purposes of this section, the following provisions also apply:

(1) **Test animals.** Adult male and female rats shall be used for testing. The rats shall be 9 to 11 weeks old and their weight range should be comparable from group to group. The animals shall be purchased from a reputable dealer and shall be permanently identified upon arrival. The animals shall be selected at random for the testing groups, and any animal showing signs of ill health shall not be used.

(2) **Species and strain.** The rat strain used shall be the same as the strain used in the subchronic and chronic tests required under § 798.2450(d)(1)(i) and § 798.3300(b)(1)(i).

(ii) **Reporting requirements.** (A) The inhalation and dermal pharmacokinetics tests shall be completed and the final report submitted to EPA by August 21, 1992.

(d) **Effective date.** (1) The effective date of this final rule is November 17, 1988, except for the provisions of paragraphs (c)(5)(i)(D), (c)(5)(ii)(A)(4), (c)(5)(ii)(C), (c)(8)(i) and (c)(8)(ii)(A) of this section. The effective date for paragraphs (c)(5)(i)(D), (c)(5)(ii)(A)(4) and (c)(5)(ii)(C) of this section is May 21, 1990. The effective date for paragraphs (c)(8)(i) and (c)(8)(ii)(A) of this section is June 12, 1992.

(2) The guidelines and other test methods cited in this section are referenced as they exist on the effective date of the final rule.

e. In § 799.3300 by revising paragraphs (e)(2)(ii)(A) and (f) to read as follows:

**§ 799.3300 Unsubstituted Phenylenediamines.**

- (e) . . . .
- (2) . . . .

(ii) **Reporting requirements.** (A) The fish partial life-cycle flow-through test shall be completed and final results shall be submitted to EPA no later than December 1, 1992.

(f) **Effective dates.** (1) The effective date of this final rule is January 16, 1990, except for paragraphs (c)(1)(i)(B), (c)(1)(ii)(A), (c)(1)(ii)(C), (c)(1)(ii)(F), (c)(3)(ii)(A), (e)(1)(ii), (e)(2)(ii)(A) and (e)(2)(ii)(B) of this section. The effective date for paragraphs (c)(1)(i)(B), (c)(1)(ii)(C) and (c)(1)(ii)(F) of this section is May 21, 1990. The effective date for paragraphs (c)(1)(ii)(A), (c)(3)(ii)(A), (e)(1)(ii) and (e)(2)(ii)(B) of this section is May 21, 1991. The effective date for paragraph (e)(2)(ii)(A) of this section is June 12, 1992.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

f. In § 799.4360 by revising paragraphs (c)(8)(ii), (d)(5)(ii)(A), (d)(6)(ii)(A) and (f) to read as follows:

**§ 799.4360 Tributyl phosphate.**

- (c) . . . .
- (8) . . . .

(ii) **Reporting requirements.** (A) The pharmacokinetics test required in paragraph (c)(8)(i) of this section shall be completed and the final report submitted to EPA by June 27, 1992.

(B) Interim 6 month progress reports shall be submitted to EPA beginning at 6 months after the effective date of the final rule and continuing until submission of the final report.

- (d) . . . .
- (5) . . . .

(ii) **Reporting requirements.** (A) The daphnid chronic toxicity test, if required, shall be completed and the final report submitted to EPA by September 27, 1991.

- (6) . . . .

(ii) **Reporting requirements.** (A) The fish early-life stage flow-through toxicity test shall be completed and the final report submitted to EPA by December 27, 1991.

(f) **Effective date.** (1) The effective date of this final rule is September 27, 1989, except for paragraphs (c)(2)(ii)(A), (c)(3)(ii)(A), (c)(8)(i), (c)(8)(ii)(A), (d)(5)(ii)(A), (d)(6)(ii)(A), (e)(1)(ii), (e)(2)(ii)(A), and (e)(3)(ii) of this section.

The effective date for paragraphs (c)(2)(ii)(A), (c)(3)(ii)(A), (c)(8)(i), (e)(1)(ii), (e)(2)(ii)(A) and (e)(3)(ii) of this section is May 21, 1991. The effective date for paragraphs (c)(8)(ii)(A), (d)(5)(ii)(A) and (d)(6)(ii)(A) of this section is June 12, 1992.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

**§ 799.5000 [Amended]**

g. In the table to § 799.5000, change the CAS No. "556-57-2" to read "556-67-2."

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

42 CFR Parts 400, 405, 407, 410, 417, 420, 424, 488, 491, and 498

[BPD-728-FC]

RIN 0938-AF14

**Medicare Program; Payment for Federally Qualified Health Center Services**

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

**SUMMARY:** These regulations establish a new category of facility known as a Federally qualified health center (FQHC), the services of which are covered under the Medicare program. This new type of entity is one that is receiving a grant under section 329, 330, or 340 of the Public Health Service (PHS) Act, a non-grant receiving entity that is determined by the Secretary to meet the PHS Act requirements for receiving such a grant, and certain facilities that have previously been identified as Federally funded health centers. These regulations also establish requirements for coverage and payment of FQHC services under the Medicare program. Related Medicaid rules are being developed in a separate rulemaking document.

These regulations implement section 4161 of the Omnibus Budget Reconciliation Act of 1990 (OBRA Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508.

**DATES:** These regulations are effective June 12, 1992. Written comments will be considered if we receive them at the