

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00499; FRL-5740-1]

Test Guidelines; Notice of Availability**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of availability.

SUMMARY: EPA has established a unified library for test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS), and is announcing the availability of final test guidelines for the Series 870—Health Effects Test Guidelines. The final guidelines have been harmonized between the Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics (OPPT) and, to the extent possible, with the Organization for Economic Cooperation and Development (OECD) Guidelines for the Testing of Chemicals. The test guidelines have been reviewed at various Scientific Advisory Panel (SAP) meetings, the most recent of which was held on October 29 and 30, 1996, as announced by notice in the **Federal Register** (61 FR 31522, June 20, 1996) (FRL-5367-7). The guidelines have been revised where appropriate in response to SAP and public comments. This notice also describes the unified library of OPPTS test guidelines.

ADDRESSES: The guidelines are available from the U.S. Government Printing Office (GPO), Washington, DC 20402 on disks or paper copies: call (202) 512-0132. The guidelines are also available electronically in PDF (portable document format) from EPA's World Wide Web site (<http://www.epa.gov/epahome/research.htm>) under the heading "Researchers and Scientists/ Test Methods and Guidelines/OPPTS Harmonized Test Guidelines."

FOR FURTHER INFORMATION CONTACT: For general information: By mail:

Toxic Substances Control Act (TSCA) information: Contact the TSCA Hotline at: TAIS/7408, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone number: (202) 554-1404; fax (202) 554-5603; e-mail: TSCA-hotline@epa.gov.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) information: Contact the Communications Services Branch (7506C), Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone number: (703) 305-5017; fax (703) 305-5558.

For technical questions on Series 870 Genetic Toxicity test guidelines: Michael

Cimino, (202) 260-3451; e-mail: cimino.michael@epa.gov.

For technical questions on other Series 870 test guidelines: William Sette, (703) 305-6375; e-mail: sette.william@epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and various support documents are available from the EPA Home Page at the **Federal Register**—Environmental Documents entry for this document under "Laws and Regulations" (<http://www.epa.gov/fedrgstr/EPA-TOX/1998/>).

I. EPA's Process for Developing a Unified Library of Test Guidelines

EPA's Office of Prevention, Pesticides and Toxic Substances has been engaged in a multi-year project to harmonize and/or update test guidelines among the Office of Pesticide Programs, the Office of Pollution Prevention and Toxics, and the Organization for Economic Cooperation and Development. The goals of the project include the formulation of harmonized OPP and OPPT guidelines for those in common between the two programs, the harmonization of OPPT and/or OPP guidelines with those of the OECD, as well as the updating of any guidelines unique to OPP or OPPT programs.

Test guidelines that are changed substantively from the existing test guidelines in the Pesticide Assessment Guidelines or 40 CFR 158.795 through 158.799 in the harmonization process or through other updating/amending activities, or which are new (e.g., for a previously unaddressed test endpoint) are made available for public comment by notice in the **Federal Register**. Additionally, EPA submits substantively revised and new test guidelines to peer review by the FIFRA SAP and other expert scientific panels. Guidelines which are reformatted but not changed in any substantive way are not made available for public comment or submitted to peer review.

All final guidelines are available through the Internet on the EPA World Wide Web Home Page as a unified library of OPPTS test guidelines for use by either EPA program office. Printed versions of the unified library of OPPTS test guidelines are also available to the public through GPO, see "ADDRESSES" at the beginning of this document. For purposes of this **Federal Register** notice, "publication" of the unified library of guidelines generally describes the availability of these final guidelines through GPO and the Internet. Because harmonization and updating is an ongoing task, some guidelines available via GPO and the Internet may be revised

in the future. These efforts will ensure that industry is provided with test guidelines that are current.

The test guidelines appearing in the unified library are given numerical designations that are different from the designations provided in the Code of Federal Regulations (CFR) at 40 CFR parts 158, 795, 796, 797, 798, and 799. OPPTS test guidelines will be published in 10 disciplinary series as follows:

Series 810—Product Performance Test Guidelines

Series 830—Product Properties Test Guidelines

Series 835—Fate, Transport and Transformation Test Guidelines

Series 840—Spray Drift Test Guidelines

Series 850—Ecological Effects Test Guidelines

Series 860—Residue Chemistry Test Guidelines

Series 870—Health Effects Test Guidelines

Series 875—Occupational and Residential Exposure Test Guidelines

Series 880—Biochemicals Test Guidelines

Series 885—Microbial Pesticide Test Guidelines

The Agency issues **Federal Register** notices periodically announcing any new test guidelines added to the OPPTS unified library. As each set of guidelines is published, it will be accompanied by a "Master List" which cross references the new OPPTS guideline numbers to the original OPP, OPPT, and OECD numbers.

II. OPP and OPPT Procedures

For pesticide registration, explicit test requirements are set out in 40 CFR part 158 which refers to specific guidelines by guideline number. Once final revised guidelines are available through GPO and the Internet, the earlier Pesticide Assessment Guidelines that were available through the National Technical Information Service (NTIS) will be removed from distribution. Studies initiated 45 days or more after publication of the notice of availability in the **Federal Register** should be performed in accordance with the revised guidelines; however, registrants should discuss effective dates for long term studies with the EPA Product Manager. As test guidelines are published, the Agency will inform industry and the general public by means of **Federal Register** notices. In addition, Data Call In letters to pesticide registrants will carry a dual numbering system for test guidelines until all test guidelines have been published. Part 158, which is currently being revised, will also carry a dual numbering system

for test guidelines when it is proposed in the **Federal Register**.

In contrast, OPPT had previously published its pre-harmonization test guidelines in 40 CFR parts 795 through 798. Recent TSCA test guidelines, based on harmonized test guidelines, have been published in part 799. TSCA test guidelines are referenced in test standards promulgated in chemical-specific test rules in part 799. To the extent that a person is subject to a test rule which references a pre-harmonization guideline published in 40 CFR parts 795 through 798, the test rule still requires compliance with the pre-harmonization test guideline that was referenced by the rule. However, if the person subject to the test rule is interested in seeking a modification to the requirement to comply with the test standard promulgated in the test rule, EPA encourages that person to consult the modification procedures outlined in 40 CFR part 790. EPA has removed and will continue to remove from the CFR those pre-harmonization guidelines that are no longer referenced in an applicable test rule.

III. Peer Review of Series 870 Health Effects Test Guidelines

The Agency has updated and harmonized test guidelines for health effects (870 Series) and submitted the revisions to peer review by the FIFRA SAP on October 29 and 30, 1996. EPA also made these revised guidelines available to the public for comment through the OPP docket and on the Internet through the EPA Home Page. Guidelines in this series have been revised in response to peer review and public comment. In addition, the series includes four new guidelines: Neurophysiology, Sensory Evoked Potentials (OPPTS 870.6855); Domestic Animal Safety (OPPTS 870.7200); Dermal Penetration (OPPTS 870.7600); and Immunotoxicity (OPPTS 870.7800). Two guidelines have been deleted: Preliminary Developmental Toxicity Screen (OPPTS 870.3500) and Inhalation Developmental Toxicity Study (OPPTS 870.3600). One guideline has been removed from the harmonized category: Acute Inhalation with Histopathology (OPPTS 870.1350). Three guidelines have been totally revised and updated: Prenatal Developmental Toxicity (OPPTS 870.3700); Reproduction and Fertility Effects (OPPTS 870.3800); and

Metabolism and Pharmacokinetics (OPPTS 870.7485). The sub-chronic guidelines for all routes of exposure have been updated to match the new OECD Guidelines 408 and 409. Under genetic toxicology testing, two guidelines addressing reverse mutation have been combined into one guideline: Bacterial Reverse Mutation Test (OPPTS 870.5100). Six guidelines have been harmonized with the most recent OECD updated tests. One new guideline has been added: Mammalian Spermatogonial Chromosome Aberration Test (OPPTS 870.5380). One OPPT guideline (40 CFR 798.5955 Heritable Translocation Test in *Drosophila melanogaster*) was not updated due to lack of use. The remaining twelve mutagenicity guidelines were not changed substantively, but were reformatted for consistency with other harmonized 870 Series guidelines. A detailed description of the response to comments and the changes to guidelines are available under docket control number OPP-00499 in the Public Information and Records Integrity Branch, Information Resources and Services Division, Office of Pesticide Programs, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA; telephone: (703) 305-5805, or by mail: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

IV. Request for Comment on Potential Voluntary Consensus Standards to Consider for Future Regulatory Actions

This notice of availability does not involve a proposed regulatory action that would require the Agency to consider voluntary consensus standards pursuant to 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). Section 12(d) 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

Congress, through OMB, explanations 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, these guidelines represent an Agency effort to harmonize the test guidelines between OPP and OPPT, as well as harmonizing the OPP and OPPT test guidelines with those of the OECD. The process for developing and amending these test guidelines includes the extensive involvement of the scientific community, including peer review by the FIFRA SAP and other expert scientific panels, and providing extensive public comment.

In the future, these test guidelines could be incorporated into regulatory actions taken by EPA pursuant to TSCA section 4. Although the NTTAA requirements do not specifically apply to the issuance of these particular test guidelines today, EPA invites your comment on whether or not there are any voluntary consensus standards that should be considered during the development of any future action under TSCA. Future actions under TSCA section 4 would go through notice and comment rulemaking or be negotiated as voluntary testing enforcement agreements/consent orders/decrees, allowing for additional public comment on this issue. Nevertheless, the Agency is interested in whether or not there are any voluntary consensus standards that EPA should consider in leu of these test guidelines when the Agency develops any future regulatory action that incorporates these test guidelines. Any comments provided will assist the Agency in complying with the NTTAA by facilitating the Agency's identification of voluntary consensus standards that should be considered during the development of a proposed regulatory action that incorporates any standards included in these test guidelines. Please submit your comments to the technical person for TSCA that is identified in the "FOR FURTHER INFORMATION CONTACT" section at the beginning of this document.

V. Notice of Availability of Final Test Guidelines

This notice announces the availability of final versions of all test guidelines in the 870 Health Effects Series. The following is the list of test guidelines being made available at this time.

Series 870—Health Effects Test Guidelines

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OPPT	OPP	OECD	712-C-
Group A—Acute Toxicity Test Guidelines.					
870.1000	Acute toxicity testing—background	none	none	none	98-189
870.1100	Acute oral toxicity	798.1175	81-1	401	98-190
870.1200	Acute dermal toxicity	798.1100	81-2	402	98-192
870.1300	Acute inhalation toxicity	798.1150	81-3	403	98-193
870.2400	Acute eye irritation	798.4500	81-4	405	98-195
870.2500	Acute dermal irritation	798.4470	81-5	404	98-196
870.2600	Skin sensitization	798.4100	81-6	406	98-197
Group B—Subchronic Toxicity Test Guidelines.					
870.3100	90-Day oral toxicity in rodents	798.2650	82-1	408	98-199
870.3150	90-Day oral toxicity in nonrodents	none	82-1	409	98-200
870.3200	21/28-Day dermal toxicity	none	82-2	410	98-201
870.3250	90-Day dermal toxicity	798.2250	82-3	411	98-202
870.3465	90-Day inhalation toxicity	798.2450	82-4	413	98-204
870.3700	Prenatal developmental toxicity study	798.4900	83-3	414	98-207
870.3800	Reproduction and fertility effects	798.4700	83-4	416	98-208
Group C—Chronic Toxicity Test Guidelines.					
870.4100	Chronic toxicity	798.3260	83-1	452	98-210
870.4200	Carcinogenicity	798.3300	83-2	451	98-211
870.4300	Combined chronic toxicity/carcinogenicity	798.3320	83-5	453	98-212
Group D—Genetic Toxicity Test Guidelines.					
870.5100	Bacterial reverse mutation test	798.5100, .5265	84-2	471, 472	98-247
870.5140	Gene mutation in <i>Aspergillus nidulans</i>	798.5140	84-2	none	98-215
870.5195	Mouse biochemical specific locus test	798.5195	84-2	none	98-216
870.5200	Mouse visible specific locus test	798.5200	84-2	none	98-217
870.5250	Gene mutation in <i>Neurospora crassa</i>	798.5250	84-2	none	98-218
870.5275	Sex-linked recessive lethal test in <i>Drosophila melanogaster</i>	798.5275	84-2	477	98-220
870.5300	In vitro mammalian cell gene mutation test	798.5300	84-2	476	98-221
870.5375	In vitro mammalian chromosome aberration test	798.5375	84-2	473	98-223
870.5380	Mammalian spermatogonial chromosomal aberration test	798.5380	84-2	483	98-224
870.5385	Mammalian bone marrow chromosomal aberration test	798.5385	84-2	475	98-225
870.5395	Mammalian erythrocyte micronucleus test	798.5395	84-2	474	98-226
870.5450	Rodent dominant lethal assay	798.5450	84-2	478	98-227
870.5460	Rodent heritable translocation assays	798.5460	84-2	none	98-228
870.5500	Bacterial DNA damage or repair tests	798.5500	84-2	none	98-229
870.5550	Unscheduled DNA synthesis in mammalian cells in culture	798.5550	84-2	482	98-230
870.5575	Mitotic gene conversion in <i>Saccharomyces cerevisiae</i>	798.5575	84-2	481	98-232
870.5900	In vitro sister chromatid exchange assay	798.5900	84-2	479	98-234
870.5915	In vivo sister chromatid exchange assay	798.5915	84-2	none	98-235
Group E—Neurotoxicity Test Guidelines.					
870.6100	Acute and 28-day delayed neurotoxicity of organophosphorus substances	798.6450, .6540, .6560	81-7, 82-5, 82-6	418, 419	98-237
870.6200	Neurotoxicity screening battery	798.6050, .6200, .6400	81-8, 82-7, 83-1	424	98-238
870.6300	Developmental neurotoxicity study	none	83-6	none	98-239
870.6500	Schedule-controlled operant behavior	798.6500	85-5	none	98-240
870.6850	Peripheral nerve function	798.6850	85-6	none	98-241
870.6855	Neurophysiology: Sensory evoked potentials	798.6855	none	none	98-242
Group F—Special Studies Test Guidelines.					
870.7200	Companion animal safety	none	none	none	98-349
870.7485	Metabolism and pharmacokinetics	798.7485	85-1	417	95-244
870.7600	Dermal penetration	none	85-3	none	98-350
870.7800	Immunotoxicity	none	85-7	none	98-351

List of Subjects

Environmental protection, Test guidelines.

Dated: July 29, 1998.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.
[FR Doc. 98-20898 Filed 8-4-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-6135-9]

Notice of Proposed NPDES General Permit for Discharges From Petroleum Bulk Stations and Terminals in Texas (TXG340000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of draft NPDES general permit.

SUMMARY: EPA Region 6 is proposing to issue a general NPDES permit authorizing discharges of facility waste water and contact storm water from petroleum bulk stations and terminals in Texas. This permit covers facilities having Standard Industrial Classification (SIC) Code 5171.

As proposed, the permit has limits on Total Petroleum Hydrocarbons, benzene, Total BTEX (sum of benzene, toluene, ethyl benzene and xylene), Total Lead and pH. There is also a requirement of no acute toxicity as determined by requiring greater than 50% survival in 100% effluent using a 24 hour acute test. In addition, the permit has limits on arsenic, barium, cadmium, chromium, copper, manganese, mercury, nickel, selenium, silver and zinc as contained in Texas Natural Resource Conservation Commission (TNRCC) Regulations for Hazardous Metals (30 TAC 319, Subchapter B), as well as requirements for no discharge of floating solids or visible foam in other than trace amounts, and no discharge of visible oil. There is also the requirement to develop and implement a pollution prevention plan for the storm water discharges authorized by this permit.

DATES: Comments on this proposed permit must be submitted by October 5, 1998.

ADDRESSES: Comments on this proposed permit should be sent to the Regional Administrator, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

FOR FURTHER INFORMATION CONTACT: Ms. Wilma Turner, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, telephone (214) 665-7516. Copies of the complete fact sheet and proposed permit may be obtained from Ms. Turner. The fact sheet and proposed permit can also be found on the Internet at <http://www.epa.gov/earth1r6/6wq/6wq.htm>. In addition, the current administrative record on the proposal is available for examination at the Region's Dallas offices during normal working hours after providing Ms. Turner 24 hours advanced notice.

SUPPLEMENTARY INFORMATION: Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Operators of petroleum bulk stations and terminals.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your (facility, company, business, organization, etc.) is regulated by this action, you should carefully examine the applicability criteria in Part I, Section A.1 of this permit. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Section 301(a) of the Clean Water Act (CWA or the Act), 33 U.S.C. 1311(a), makes it unlawful to discharge pollutants to waters of the United States in the absence of authorizing permits. CWA section 402, 33 U.S.C. 1342, authorizes EPA to issue National Discharge Elimination System (NPDES) permits allowing discharges on condition they will meet certain requirements, including CWA sections 301, 304, and 401 (33 U.S.C. 1331, 1314 and 1341). Those statutory provisions require that NPDES permits include effluent limitations requiring that authorized discharges: (1) Meet

standards reflecting levels of technological capability, (2) comply with EPA-approved state water quality standards and (3) comply with other state requirements adopted under authority retained by states under CWA 510, 33 U.S.C. 1370.

Two types of technology-based effluent limitations must be included in the permit proposed here. With regard to conventional pollutants, i.e., pH, BOD, oil and grease, TSS and fecal coliform, CWA section 301(b)(1)(E) requires effluent limitations based on "best conventional pollution control technology" (BCT). With regard to nonconventional and toxic pollutants, CWA section 301(b)(2)(A), (C), and (D) require effluent limitations based on "best available pollution control technology economically achievable" (BAT), a standard which generally represents the best performing existing technology in an industrial category or subcategory. BAT and BCT effluent limitations may never be less stringent than corresponding effluent limitations based on best practicable control technology (BPT), a standard applicable to similar discharges prior to March 31, 1989 under CWA 301(b)(1)(A).

National guidelines establishing BPT, BCT and BAT standards have not been promulgated for discharges from petroleum bulk stations and terminals. The BCT and BAT requirements for these discharges have, therefore, been established using best professional judgement, as required by CWA section 402(a)(1). All of the limitations in this proposed permit, except for the requirement to develop and implement a storm water pollution prevention plan, are also current requirements in TNRCC Regulations 30 TAC 321, Subchapter M, for discharges from petroleum bulk stations and terminals. The storm water pollution prevention plan requirements are those currently required by the NPDES Storm Water Multi-Sector General Permit for storm water discharges associated with petroleum bulk stations and terminals. All of the discharges authorized by this permit are also those authorized by 30 TAC 321, Subchapter M.

In addition to requiring the development and implementation of a storm water pollution prevention plan, the following limits are proposed:

	Daily maximum (mg/l)	Monitoring frequency
Total petroleum hydrocarbons	15	1/week (3).
Benzene	0.05	1/week (3).
Total BTEX (1)	0.5	1/week (3).