

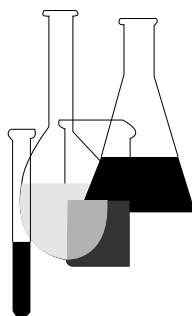


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# Ecological Effects Test Guidelines

## OPPTS 850.1500

### Fish life cycle toxicity



**“Public Draft”**

## INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) 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 purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

**Public Draft Access Information:** This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher ([gopher.epa.gov](http://gopher.epa.gov)) under the heading “Environmental Test Methods and Guidelines” or in paper by contacting the OPP Public Docket at (703) 305-5805 or by e-mail: [guidelines@epamail.epa.gov](mailto:guidelines@epamail.epa.gov).

**To Submit Comments:** Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: [guidelines@epamail.epa.gov](mailto:guidelines@epamail.epa.gov).

**Final Guideline Release:** This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202-512-1387, telnet and ftp: [fedbbs.access.gpo.gov](http://fedbbs.access.gpo.gov) (IP 162.140.64.19), or call 202-512-0135 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher ([gopher.epa.gov](http://gopher.epa.gov)) under the heading “Environmental Test Methods and Guidelines.”

**OPPTS 850.1500 Fish life cycle toxicity.**

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP 72-5 Life-Cycle Tests of Fish (Pesticide Assessment Guidelines, Subdivision E—Hazard Evaluation; Wildlife and Aquatic Organisms) EPA report 540/09-82-024, 1982.

(b) **When required.** (1) Data obtained from a life-cycle test of fish are required by 40 CFR 158.145 to support the registration of an end-use product intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:

(i) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test; or

(ii) If studies of other organisms indicate the reproductive physiology of fish may be affected.

(2) See 40 CFR 158.50, “Formulators’ exemption”, to determine whether these data must be submitted. Section II-A of this Subdivision provides an additional discussion on this subject.

(c) **Test standards.** Data sufficient to satisfy the requirements in 40 CFR 158.145 should be derived from tests which comply with the general test standards in § 70-3 and the following test standards:

(1) **Test substance.** Data shall be derived from testing conducted with the technical grade of each active ingredient in the product.

(2) **Duration of tests.** Fish should be cultured in the presence of the test substance from one stage of the life cycle to at least the same stage of the next generation (e.g. egg to egg).

(3) **Species.** Testing should be performed on a freshwater fish (e.g. fathead minnow). An estuarine species (e.g. sheepshead minnow) may be used if the pesticide is expected to enter the estuarine environment.

(4) **Concentration analysis.** The concentration of the test substance in the water should be determined at the start of the study and periodically throughout the study to verify concentrations.

(d) **Reporting and evaluation of data.** In addition to the basic information provided in § 70-4, the test report should contain the following information (where appropriate):

- (1) Reproductive effects;
- (2) Detailed records of spawning, egg numbers, fertility, and fecundity;
- (3) No-effect level, and mortality data;
- (4) Statistical evaluation of effects;
- (5) Locomotion, behavioral, physiological, and pathological effects;
- (6) Definition of the criteria used to determine effects;
- (7) Summary of general observation of signs of intoxication or other effects;
- (8) Stage of life cycle in which organisms were tested;
- (9) Duration of the test; and
- (10) Concentration analysis.

(e) **Acceptable protocol**—(1) **Freshwater fish life-cycle test.** An example of an acceptable protocol is found in the following reference:

National Water Quality Laboratory Committee on Aquatic Bioassays. 1971. Recommended bioassay procedure for fathead minnow *Pimephales promelas* (Rafinesque) chronic tests. (Revised January, 1972). Pp. 15-24 in Biological Field and Laboratory Methods. U. S. Environmental Protection Agency, Office of Res. and Dev. EPA-670/4-73-001.

(2) **Estuarine fish life-cycle test.** Examples of acceptable protocols are found in the following references:

(i) Schimmel, S.C., and D.J. Hansen. 1974. Sheepshead minnow *Cyprinodon variegatus*: an estuarine fish suitable for chronic (entire lifecycle) bioassays. *Proc. 28th Ann. Cong. S.E. Assoc. Game-Fish Comm.* Pp. 392-398.

(ii) Hansen, D.J., P.R. Parrish, S.C. Schimmel, and L.R. Goodman. 1978. Life-cycle toxicity test using sheepshead minnows (*Cyprinodon variegatus*). Pp. 109-116 in Bioassay Procedures for the Ocean Disposal Permit Program. U.S. Environmental Protection Agency, Office of Research and Development. EPA-600/9-78-010.