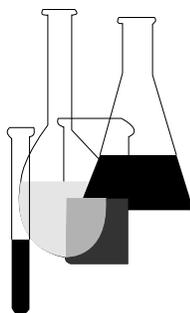




# Residue Chemistry Test Guidelines

## OPPTS 860.1650 Submittal of Analytical Reference Standards



## 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.*).

**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 (IP 162.140.64.19), internet: <http://fedbbs.access.gpo.gov>, or call 202-512-0132 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 860.1650 Submittal of analytical reference standards.**

(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 Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C., 301 *et seq.*)

(2) **Background.** The source material used in developing this harmonized OPPTS guideline is OPP 171–13 Submittal of Analytical Reference Standards (Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, EPA Report 540/9–82–023, October 1982). This OPPTS guideline should be used in conjunction with OPPTS 860.1000, Background.

(b) **Purpose.** The purpose of the requirements for submitting analytical reference standards is to ensure that: Proper analytical reference grade materials are available for the Agency to validate residue and environmental chemistry analytical methods and that Federal and State enforcement laboratories have a known consistent source of analytical reference standards to validate methods employed in enforcement and monitoring activities.

(c) **Submittal of analytical reference standards.** (1) To avoid delay in processing petitions for tolerances for new pesticides, 5 g samples of the active ingredient analytical grade standard and 1 g, or a reasonable amount, of all metabolites that are named in the tolerance expression (part of the total toxic residue (TTR)) should be submitted to the Pesticide and Industrial Chemicals Repository (MD–8), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. Registrants should also send 1 g, or a reasonable amount, of any stable derivative that is used to identify and quantitate the target compounds to the EPA repository.

(2) The letter of transmittal should include the assay of the standards, names of the analytical methods used, a statement of principal impurities, purification procedures employed, storage requirements, and special precautions for safe handling. A copy of the transmittal letter should be inserted in Section A of the petition. Larger quantities of standards are usually required once the tolerance is established. Replacement of standards may be required periodically if supplies are exhausted or if decomposition occurs during storage. For nonacutely toxic metabolites which are difficult to synthesize, quantities less than 1 g will be acceptable.

(3) (i) Material Safety Data Sheets (MSDSs) must accompany all analytical standards as specified by Occupational Safety and Health Administration (OSHA) in 29 CFR 1910.1200.

(ii) This requirement is in addition to the requirement for submittal of analytical standards for the pure active ingredient (PAI) and technical grade active ingredient (TGAI) for product chemistry purposes (see OPPTS guideline 830.1900).