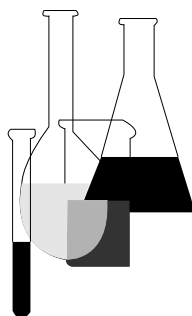




# Product Properties Test Guidelines

## OPPTS 830.1700 Preliminary Analysis



## 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 document 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 available 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 830.1700 Preliminary analysis.**

(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 40 CFR 158.170 Preliminary analysis.

(b) **Information required.** (1) If the product consists solely of the technical grade active ingredient (TGAI) or is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI (the Agency recognizes that this may not be appropriate for certain biological pesticides). The preliminary analysis of 5 batches (if batch production) or 5 samples (if continuous production) should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended.

(2) Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted.

(c) **Data reporting format.** (1) The manufacturer's/registrant's/petitioner's reports should include all information necessary to provide complete and accurate topical discussions of the pesticide product.

(i) *Title/cover page.* Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These requirements are described in Pesticide Regulation Notice PR 86-5 (see paragraph (d)(1) of this guideline).

(ii) *Table of contents.*

(A) *Summary and introduction.*

(1) Scope and source of method (e.g., "Official Methods of Analysis of AOAC-International," or "EPA Manual of Chemical Methods for Pesticides and Devices" (see paragraphs (d)(1) and (d)(2) of this guideline).

(2) Principles of the analytical procedure (describe) including identification of the chemical species determined and the limits of detection and sensitivity.

(B) *Materials and methods.*

- (1) Equipment (list and describe).
- (2) Reagents and standards (list and describe source and preparation).
- (3) Analytical procedure (detail in a stepwise fashion, with special emphasis on reagents or procedural steps requiring special precautions to avoid safety or health hazards):
  - (i) Preparation of sample.
  - (ii) Extraction (demonstrate efficiency, if relevant).
  - (iii) Clean-up.
  - (iv) Derivatization (if any).
- (4) Instrumentation (to include information on):
  - (i) Description (e.g., make/model, type/specificity of detectors, columns, (packing materials, size), carrier gases, etc.).
  - (ii) Operating conditions (e.g., flow rates, temperatures, voltage, etc.).
  - (iii) Calibration procedures.
- (5) Interferences (describe tests):
  - (i) Sample matrices.
  - (ii) Other pesticides.
  - (iii) Solvents.
  - (iv) Labware.
- (6) Confirmatory techniques (describe).
- (7) Time required for analysis (to carry a sample/set completely through the analytical procedure, including the determinative step).
- (8) Modifications or potential problems, if any, in analytical methods (detail circumstances and corrective action to be taken).
- (9) Methods of calculation (describe in a stepwise fashion):
  - (i) Calibration factors.
  - (ii) Analyte in sample.
- (10) Other (any and all relevant information the petitioner considers appropriate and relevant to provide a complete and thorough description of residue analytical methodology and the means of calculating the residue results).

(C) *Results and discussion* (describe expected performance of method).

(1) Accuracy (expected mean and range of recoveries).

(2) Precision.

(3) Limits of detection and quantification (provide definition).

(4) Ruggedness testing , if performed.

(5) Limitations.

(D) *Conclusions*. Discuss applicability of analytical procedure for measuring specific test compounds in various test substrates, ready availability of equipment, interferences, etc.

(E) *Certification*. Certification of authenticity by the study director (including signature, typed name, title, affiliation, address, telephone number, date).

(F) *Tables and figures*.

(G) *References*.

(H) *Appendices*.

(1) Representative chromatograms, spectra, etc. (as applicable).

(2) Other (any relevant material not fitting in any of the other sections to this report).

(2) [Reserved]

(d) **References**. The following references should be consulted for additional background material on this test guideline.

(1) Environmental Protection Agency, Pesticide Regulation Notice PR 86-5, Standard Format for Data Submitted Under the FIFRA and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), July 29, 1986.

(2) Official Methods of Analysis of AOAC-International, Association of Official Analytical Chemists (AOAC)-International, Arlington, VA, latest edition.

(3) *EPA Manual of Chemical Methods for Pesticides and Devices*, published by Association of Official Analytical Chemists (AOAC), Arlington, VA (1992).