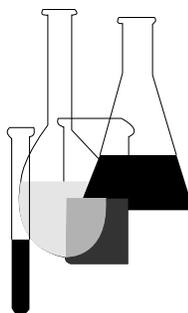




Residue Chemistry Test Guidelines

OPPTS 860.1560

Reasonable Grounds in
Support of the Petition



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) under the heading "Environmental Test Methods and Guidelines."

OPPTS 860.1560 Reasonable grounds in support of the petition.

(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 171-7 Reasonable Grounds in Support of the Petition (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) **Reasonable grounds in support of the petition—section G of a petition.** (1) The petitioner should present the rationale of how the residue data support the proposed tolerance. The presentation should include:

(i) Brief discussions on the adequacy of the analytical method with respect to sensitivity and determination of the total toxic residue.

(ii) An explanation of any aberrant residue values reported.

(iii) An explanation for the omission or substitution of requirements set forth in these guidelines.

(iv) Any other residue considerations pertinent to the proposed use.

(v) Where appropriate, a discussion should be furnished on the status of other components of the formulation.

(2) In those instances where the dietary risk from use of the pesticide is likely to be unacceptable, assuming tolerance level residues on the entire crop, the petitioner should provide any information or data that could be used to estimate a more realistic dietary exposure. In the case of concerns with chronic risk, determination of the average residue obtained in crop field trials would be useful. Also, information on actual or projected market shares for existing or proposed uses, respectively, can be submitted for review by OPP's Biological and Economic Analysis Division.