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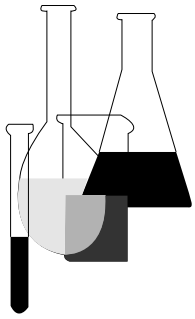
Microbial Pesticide Test Guidelines

OPPTS 885.2500
Magnitude of Residues in Plants



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), or call 202–512–1530 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 885.2500 Magnitude of residues in plants.

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

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 153A–10.

(b) **Microbial pest control agent residues of toxicological concern.** Microbial pest control agent (MPCA) residues of toxicological concern must be determined in or on raw agricultural commodities (RACs) of all crops on which use is proposed or, if preferred, RACs of each representative crop belonging to a given crop group under 40 CFR 180.34(f) to allow the establishment of a crop group tolerance. If residues are detectable in or on the RAC or if concentration in processed products is possible, then processing studies will also be required. In general, the procedures described under OPPTS 860.1340 should be used for guidance making certain that a representative of each major formulation class is tested according to the proposed use pattern. Note that the words pesticide and chemical under OPPTS series 860 are assumed to include MPCAs for purposes of guideline series 885. Residue increases and/or decline in or on crops will frequently be a function of growth or replication cycles of the MPCA which, in turn, is a function of the population dynamics of potentially numerous other organisms such as the host, the plant site (if different from the host), other parasites/pathogens of either the host or the MPCA itself, or competing occupants of the same or a similar habitat. It is expected that environmental conditions will play an even greater role in the magnitude of MPCA residues in or on plants than in the case of conventional chemical pesticides. Therefore, adequate geographic representation of test sites is imperative; refer to USDA's Agricultural Statistics (GPO), published annually, for the most recent state production figures for various crops. Note that in OPPTS 860.1340 it is stated that a processing study utilizing radiolabeled material may be required if processing of the RAC could result in alteration of the residue; in the case of an MPCA, radiolabeling will rarely be either possible or of utility and, therefore, other approaches must be used.

(c) **Additional information requirements.**In addition to the above information and the residue data itself, the following materials and procedural details must be provided: Location of test, application rate (weight or volume of product/A and number of viable microbes/A, etc.), formulation used, part of crop analyzed, number of samples, sampling procedure, planting time (date), application dates, harvest/sampling date(s), application method, stage of crop at application and harvest, analytical method used, untreated control data, recovery data, and sample storage time and conditions.