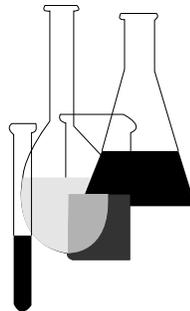




# Microbial Pesticide Test Guidelines

## OPPTS 885.2000

### Background for Residue Analysis of Microbial Pest Control Agents



## 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 885.2000 Background for residue analysis of microbial pest control agents.**

(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-1.

(b) **Requirements.** A petition for a tolerance or for an exemption from the requirement of a tolerance must be submitted as specified in 40 CFR 158.740 in connection with each application for registration of a microbial pest control agent (MPCA) where usage may result in residues in or on food for humans or feed for domestic animals used for human food. This petition must contain data satisfying the requirements of 40 CFR 158.740 which are detailed in OPPTS 885, Group B (Residue Test Guidelines) unless specifically exempted from the requirements.

(c) **Purpose.** Residue chemistry data are designed to provide the information necessary to determine the site, nature, and magnitude of residues in or on food or feed. This information includes plant metabolism data, residue data, analytical methodology, and, when indicated, animal metabolism data and animal feeding studies to determine the carry over of residues into meat, milk, poultry, and eggs.

(d) **Authority.** Pesticides including MPCAs, intended for use on food or feed crops, or where usage may reasonably be expected to result (directly or indirectly) in residues in food or feed, will not be registered unless a tolerance, or an exemption from the requirement of a tolerance, has been established by the Agency, as provided for under sections 406, 408, or 409 of the Federal Food, Drug, and Cosmetic Act ((FFDCA) 21 U.S.C. 346, 346a, and 348). The procedural regulations for filing petitions for a tolerance or an exemption are included in 40 CFR 180.7.

(e) **Approach.** The use of an MPCA on food, feed, or raw agricultural commodities requires that a tolerance, or an exemption from the requirement for a tolerance, be established by the Agency. In considering exemptions from the requirement for tolerances, the Agency recognizes that MPCAs do not necessarily pose the same potential hazards as conventional chemical pesticides. In fact, certain characteristics of many of these agents suggest that they may pose relatively less hazard. These characteristics are listed below:

(1) The efficacy of the agent often depends upon its ability to replicate in the target pest, which is not likely to remain on the crop after harvest.

(2) The living form of the agent in most instances will usually not replicate in the absence of the specific target pest (e.g. insect host).

(3) Certain environmental conditions such as sunlight, rainfall, winds, humidity, and temperature often greatly reduce the viability of the agent; therefore, the residues of living organisms are apt to be small or relatively insignificant shortly after application.

(4) Data supporting currently registered MPCAs indicate that they would not likely pose a hazard to humans or other mammals.

(5) In many instances where and when a microorganism is used as an MPCA, the microorganism is already normally present in the environment and has demonstrated no adverse effects.

(6) Residues of microorganisms used as MPCAs that are capable of replication on food or feed—a very remote possibility—may be rendered nonviable or be removed by the usual processing of such foods and feeds (i.e., washing, drying, heat sterilization, and additions of sugar, salt, and other preservatives).

(f) **Tier progression.** The Agency evaluates residue data for MPCAs used on food, feed, or raw agricultural commodities only if toxic or other harmful properties were observed in the maximum hazard toxicology tests (Tier I) prescribed in toxicology test guidelines OPPTS 885.3050 through 885.3650 of this series. If Tier I toxicology tests indicate no toxic or other harmful properties, then no residue data (with the general exception of a monitoring method) would be indicated and thus a recommendation for an exemption from the requirements of a tolerance can be made.

(g) **General residue data requirements for MPCAs—(1) When required.** Residue data are required by 40 CFR 158.740 to be included in a petition for a tolerance or for an exemption from the requirement of a tolerance, in connection with each application for registration of a manufacturing-use product or end-use product composed of or containing an MPCA, when the following conditions are met:

(i) When the product is intended for use on food or feed crops.

(ii) When use of the product is expected to result in residues in or on food or feed.

(iii) When results of Tier I toxicology studies conducted in accordance with OPPTS 885.3050 through 885.3500 indicate that there may be significant human health concerns.

(iv) Residue data may not be required and an exemption from the requirement of a tolerance may be recommended for products intended for use on food feed crops or for uses expected to result in residues in or on food or feed, when the toxicology data developed from Tier I testing, in accordance with toxicology test guidelines OPPTS 885.3050 through 885.3650 of this series, indicate that there are no significant human health

concerns. The exception to this is that a monitoring method will be required for each registered MPCA, even if exempt from tolerance.

(2) **Procedures, standards, and reporting.** In addition to the provisions set forth in OPPTS 885.0001 that are applicable, the following guidance is provided for conducting, developing, and reporting the residue data that the Agency requires to support a petition for a tolerance or for an exemption from the requirement of a tolerance. In general, the guidance in OPPTS series 860, particularly in terms of rationale and approach, is applicable to MPCAs under this subdivision. Unless addressed below, all parts of OPPTS series 860 as written are to be considered applicable to this series OPPTS 885; the term “pesticide” is assumed to include MPCAs. Discussion with appropriate Agency scientists may be helpful before steps are taken to develop residue data of the nature outlined in this series.