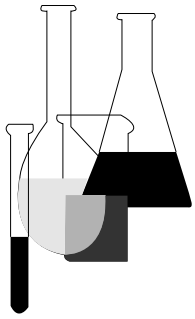
United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7101)

EPA 712–C–96–303
February 1996

Microbial Pesticide Test Guidelines

OPPTS 885.2250
Nature of the Residue in Animals



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 885.2250 Nature of the residue in animals.

(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–7.

(b) **Test procedures and reporting of data.** (1) If microbial pest control agents (MPCAs) have been determined to be of toxicological concern, or if residues of concern will be present in or one feed items, animal metabolism studies must be conducted utilizing ruminants and poultry. If residues of toxicological concern occur in or on feed items, animals generally must be dosed orally for at least 3 days with the MPCA terminal residues in feed items characterized to the extent possible. Note that, theoretically, a single MPCA propagule in or on a feed item could cause infection or allow replication in livestock; obviously, this single viable unit could be a residue of toxicological concern but would most likely not have been detected in or on the feed item. Therefore, if any potential for animal pathogenicity exists, animal metabolism studies will be required in all cases. If orally or dermally administered direct animal treatments or animal premise treatments are proposed, animals/premises must be treated according to the proposed use directions or at exaggerated rates (if necessary for residue characterization) using a typical end-product.

(2) If no replication of the MPCA occurs in or on the animal, at least muscle, fat, kidney, and liver must be analyzed within 24 h of dosage cessation. If MPCA replication occurs in the animal, several longer intervals may also be required and more extensive tissue sampling will be necessary. Some MPCAs, notably fungi, may require weeks or months to establish a detectable infection. Eggs and milk, where applicable, must be sampled at regular intervals, preferably daily. It may be possible to combine the animal metabolism and animal magnitude of residue studies (OPPTS 885.2500), if required. These studies will allow the determination of the major residues for which analytical methodology must be developed and those which must be sought in animal feeding studies, if required. The efficiency and sensitivity of the utilized methods will also be determined from these animal metabolism studies.