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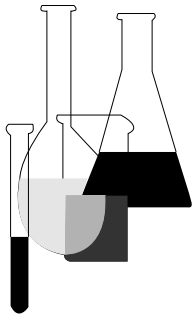
Microbial Pesticide Test Guidelines

OPPTS 885.1300 Discussion of Formation of Unintentional Ingredients



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.*).

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OPPTS 0885.1300 Discussion of formation of unintentional ingredients.

(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 are OPP guidelines 151A–1 and 151A–12.

(b) **Information needed.** The product analysis data requirements for microbial pest control agents (MPCAs) parallel those for conventional chemical pesticides in OPPTS Series 830. However, due to the unique nature, composition, and mode of action of the MPCAs, there are some important differences. For example, protozoa, bacteria, fungi, and viruses should be identified to the extent possible by taxonomic position, serotype, composition, and strain, or by any other appropriate specific means. This information would take the place of chemical name and structure information for conventional chemical pesticides. In addition, the Agency must be reasonably assured that the methods used and the data submitted are capable of demonstrating that the microbial pesticide used in the field is the same as that which was tested for safety.

(c) **Registration applications.** Each registration application shall include the following information:

(1) **Theoretical discussion.** The theoretical discussion concerns the formation of each substance, aside from the control agents and intentionally added, chemically characterized active and inert ingredients, that might reasonably be present in the pesticide product, as outlined OPPTS 830.1670. Examples of such extraneous materials are: Allergens, microbial toxins, and other metabolic products; mutant strains; microbial contaminants with particular reference to potentially infective or antagonistic forms; side products from chemical reactions employed in the manufacturing process, fermentation residues from the growth of bacteria or fungi; extraneous host residues from viruses produced in cell cultures, whole animals, or other living forms; residues of contaminants that remain following the purification or extraction process; and impurities in chemicals used in the manufacturing process. The discussion shall include the procedures used to ensure the purity of the unformulated MPCA preparation; if purity (within reasonable limits) cannot be achieved, then the means of controlling contaminant levels to an acceptable limit must be delineated.

(2) **Toxic or sensitizing substances.** If substances toxic or sensitizing to humans or other nontarget mammalian species are known or suspected to be present at any stage of the manufacturing process, then data must be submitted to show that the substances do not exist in the final product or exist only in quantities too small to pose any hazard.

(3) **Human or animal pathogens.** Human or other nontarget animal pathogens such as (but not limited to) *Shigella*, *Salmonella*, and *Vibrio* must not be present at hazardous levels in the technical grade of the active ingredient. If the production method can support the growth of human or animal pathogens, each production batch must be tested for their presence. Each application for registration of a manufacturing-use product or end-use product should contain an analysis of all human or animal pathogens that might be present at potentially hazardous levels in the product before formulation. The application should propose methodology for detecting and/or eliminating these from the product. For example, the method prescribed in 40 CFR 180.1011 to monitor each production batch of *Bacillus thuringiensis* for the pathogen *Bacillus anthracis* involves subcutaneous injection of at least 1 million viable microorganisms or spores into each of 5 laboratory mice weighing 17 to 23 g. Such tests shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.

(4) **Detection of hazardous contamination.** Methods should be proposed for controlling any hazardous contamination detected in the product. Discarding of a contaminated production batch or treating the formulation may be equally acceptable methods for controlling the contaminating microorganisms.