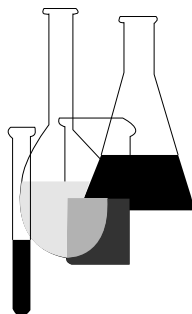




# Microbial Pesticide Test Guidelines

## OPPTS 885.4380 Honey Bee Testing, Tier I



## 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 885.4380 Honey bee testing, Tier I.**

(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 154A–24.

(b) **When required.** Data on the toxicity/pathogenicity of a microbial pest control agent (MPCA) are required when the proposed use pattern indicates that honey bees may be exposed to the pesticide, and for each manufacturing-use product that may be used legally to formulate such an end-use product. See 40 CFR 158.50 and 158.740 to determine whether these data must be submitted.

(c) **Test standards.** In addition to satisfying the applicable general test standards outlined in OPPTS 885.0001, the following apply:

(1) **Test substance.** The actual form of the material to be regarded as the test substance is discussed in OPPTS 885.0001. In addition, any substances used to enhance virulence should be tested along with the test substance.

(2) **Test species.** Testing shall be performed on the honey bee, *Apis mellifera*.

(3) **Age.** When the MPCA may be expected to affect insect larvae, test insects should include honey bee larvae.

(4) **Route of exposure.** When the MPCA may be expected to act by a dietary route of exposure or are particles of such a size that they might be carried back to the hive like pollen, the honey bees must be dosed orally. Testing in the hive may be necessary.

(5) **Controls.** A concurrent control group is recommended and should be treated with microbe-free (or nonviable microbe) material from the culture system used for propagation of the MPCA.

(6) **Duration of test.** Control and treated bees should be observed for at least 30 days after dosing.

(d) **Reporting and evaluation of data.** The reporting requirements are the same as those specified in OPPTS 885.0001.

(e) **Tier progression** (1) Data derived from Tier I testing will be used in conjunction with available information on use pattern, host range, and other factors, to assess potential for adverse effects. If data indicate that the potential for adverse effects exists, Tier II testing will be required as specified in 40 CFR 158.740. In some cases, a subchronic test may

serve to better understanding of the effects observed at the Tier I level and alleviate the need for Tier II testing.

(2) If toxic or pathogenic effects are not observed in this study, additional testing is ordinarily not necessary.

(f) **References.** The following references are provided for use in the development of acceptable test protocols for conducting a honey bee toxicity/pathogenicity test with a microbial pest control agent:

(1) Davidson, E.W. et al. Effect of *Bacillus sphaericus* strain SSII-1 on honey bees, *Apis mellifera*. *Journal of Invertebrate Pathology* 29:344–346 (1977).

(2) Menapace, D.M. et al. Adult honey bees are not susceptible to infection by *Nosema locustae*. *Journal of Economic Entomology* 71:304–306 (1978).

(3) Morton, H.L. et al. Effect of alfalfa looper nuclear polyhedrosis virus in honey bees. *Journal of Invertebrate Pathology* 25:139–140 (1975).

(4) Hitchcock, J.D. et al. Pathogenicity of *Bacillus pulvifaciens* to honey bee larvae of various ages (Hymenoptera: Apidae). *Journal of Kansas Entomological Society* 52:238–246 (1979).