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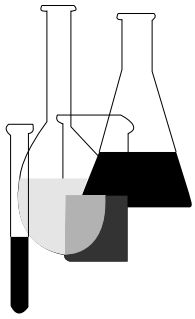
Microbial Pesticide Test Guidelines

OPPTS 885.2550 Magnitude of Residues in Meat, Milk, Poultry, and Eggs



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 885.2550 Magnitude of residues in meat, milk, poultry, and eggs.

(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–11.

(b) **Guidance for microbial pest control agents (MPCAs).** Generally, the guidance presented in OPPTS 860.1340 is applicable to MPCAs under OPPTS Series 885 noting that, again, the word pesticide is assumed to include MPCAs. If residues of toxicological concern occur in animal tissues, milk, or eggs following oral dosing in the animal metabolism studies, feeding studies are required reflecting l×, 3×, and l0× the maximum expected dietary intake of MPCA residues occurring in or on feed items. Animals must generally be dosed for 28 days and slaughtered within 24 hours of the final dose. If pathogenicity, toxicity, or very slow growth and/or disease development is a problem, appropriately shorter or longer feeding periods or perhaps even longer preslaughter intervals may be used, preferably in consultation with Agency scientists. The key issue is timing, i.e. the maximum residue/MPCA concentrations in tissues, milk, and eggs must be determined in order to allow the tolerances and, perhaps, preslaughter intervals, to be established. Similarly, if residues occur in animals following a direct animal treatment (if proposed) as determined in an animal metabolism study, studies utilizing typical end-products (EPs) must be conducted according to the proposed use directions; such treatments could be feed-through, dermal, or otherwise. If two or more routes of exposure are possible, a single study combining both routes is acceptable if the health of animals is not affected. Note that the petitioner may find it advantageous to combine the animal metabolism studies (OPPTS 885.2250) and the feeding/direct animal treatment studies.

(c) **Reporting study results.** The dosage rate must be clearly stated. In the case of a feeding study, parts per million of nonviable residues and enumeration of viable residues (colony- or plaque-forming units or infectivity units/unit weight of feed or per unit weight per day) as well as the weights of animals must be provided. In the case of direct-animal treatments (oral, dermal, or otherwise), the weight or volume of product (typical EP) and the number of viable MPCAs per unit weight, surface area, etc. of animal must be provided. Generally, ruminant and poultry studies are required if residues of toxicological concern occur in feeds or if direct animal treatments are proposed. Swine studies may also be required if there is any reason to expect higher residues and/or more rapid MPCA replication in swine than in poultry or ruminants. If agricultural premise treatments are proposed studies may be required to demonstrate the magnitude of the residue in animals following these uses. All tissues used as food must be sampled; eggs and milk must be sampled twice daily.

Sample storage time and conditions must be provided as well as the identity of the analytical methods used, recovery data, and control animal data. Also, the formulation used and number of samples must be presented.