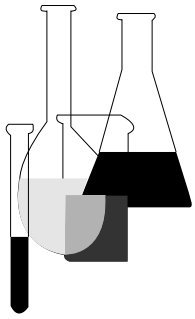
United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7101)

EPA 712–C–96–302
February 1996

Microbial Pesticide Test Guidelines

OPPTS 885.2200
Nature of the Residue in Plants



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 885.2200 Nature of the residue in plants.

(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–6.

(b) **When required.** Plant metabolism studies are required to determine the nature of the microbial pest control agent (MPCA) residues in plants whenever an MPCA use is determined to be a food use. If a use is likely to result in MPCA residues in or on food, the use is considered to be a food use. In some cases, however, it may be possible to waive the requirements for plant metabolism data if no potential MPCA residues are expected to be of toxicological concern; such a waiver is most likely to be granted for an indigenous microbe that does not produce or code for a toxin. Attempts must be made to characterize all MPCA residues in or on plants regardless of their route of entry and/or deposition or whether they were produced via metabolic or strictly physicochemical processes.

(1) Potential residues of concern may be, but are not limited to, the following:

(i) All types of propagules of the parent (active ingredient) MPCA such as vegetative cells, sexual and asexual spores, virions, and viroids.

(ii) Mutants of the MPCA in question.

(iii) The genetic material itself.

(iv) Any antigenic/allergenic, toxic, and/or mutagenic substances associated with the MPCA product either as impurities in the formulation or as components or metabolic products of the MPCA itself produced during the manufacture or storage of the product or at the site of application.

(v) Or any other replicating entity which is the recipient of MPCA genetic material (chromosomal or extrachromosomal) of potential concern (such recipients may be viruses or cells of animals, plants, or bacteria). The genetic stability (ease of genetic exchange or transfer) is thus important in determining potential residues of concern, especially in the cases of nonindigenous or genetically altered MPCAs.

(c) **Test procedures and reporting of data.** (1) The uptake, metabolism, and translocation of the MPCA must be determined, typically in a representative member of each crop group defined in 40 CFR 180.34(f) except the herbs and spices group. If the metabolism is similar in three unrelated crops, additional crops normally need not be included. In the case of demonstrated or potential plant pathogens, however, more extensive testing may be required, especially since replication of the MPCA

may occur in nontarget crop species; consultation with appropriate Agency scientists should be sought if a petition involves a plant pathogen. If possible, treated plants must be grown to normal crop maturity so that residues may be characterized in or on the raw agricultural commodities (RACs) derived from the crop in question.

(2) Plants must be treated via the proposed route (seed treatment, soil treatment, foliar plus soil treatment, etc). Since intentionally added inert ingredients could significantly influence MPCA deposition, viability/stability, absorption, and even replication at the treatment site, the test substance should be a typical end-use product (EP). In some cases, radiolabeling of the MPCA may be useful but, generally, other approaches must be employed to determine the total terminal residue and, subsequently, which terminal residues are of toxicological concern (refer to OPPTS 885.3050 through 885.3650). The application rate should be the maximum proposed rate or exaggerated rates, if necessary for residue identification.

(3) MPCAs, being much more complex than conventional chemical pesticides, create unusual analytical problems. For example, the total terminal residue may consist of drastically different entities (whole microbes, toxins, etc.) each requiring greatly differing analytical procedures. Also, since all or most MPCAs are replicating entities, the total terminal residue will frequently increase with time but not as a function of continued residue absorption and/or transformation of one residue to another as is typically the case with conventional pesticides. In some cases, the viable MPCA per se may not be of toxicological concern but a toxin produced by the MPCA may be of concern. Note, however, that the MPCA itself will be regulated even if it serves only as a source of a residue of toxicological concern.

(4) Some MPCAs may remain in the soil and/or on aerial plant parts whereas others may gain entrance into plants via active or passive routes. Once in the plant, the MPCA may be transported to other plant parts, may replicate, and may cause disease; in other cases, replication may occur only at the site of entrance. Replication may occur only in arthropod or other hosts in or on plant tissues. In some cases, the MPCA may be restricted to the soil or an isolated plant part, perhaps not a RAC, but exert its influence throughout the plant such as in the case of a translocatable toxin. MPCA residues may fluctuate with the growth cycles. It is the responsibility of the petitioner to demonstrate which, if any, plant parts bear which residues of concern, i.e. to determine the distribution of residues. These studies will demonstrate which are the major residues to be sought in field residue studies, if required, and also will provide an indication as to the efficiency and sensitivity of the methods used. Refer to OPPTS 885.2300 and 885.2350 for a discussion of some analytical methods expected to be of use for MPCA determination.