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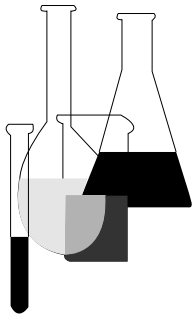
Residue Chemistry Test Guidelines

OPPTS 860.1550
Proposed Tolerances



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 860.1550 Proposed tolerances.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*)

(2) **Background.** The source materials used in developing this harmonized OPPTS guideline are OPP 171–6 Proposed Tolerances, OPP 171–8 Exemptions from the Requirement of a Tolerance, and OPP 171–9 Tolerance for Foreign Uses (Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, EPA Report 540/9–82–023, October 1982). This OPPTS guideline should be used in conjunction with OPPTS 860.1000 Background.

(b) **General**—(1) **Determining the tolerance level.** To obtain a tolerance, the petitioner proposes a tolerance level, based on residue field trial data, which reflects the maximum residue that may occur under worst-case conditions as a result of the proposed use of the pesticide. The tolerance must include significant metabolites of toxicological concern and must be high enough to cover all components of the total toxic residue (TTR). The pesticide active ingredient and any significant metabolites together comprise the TTR. If one component of the residue is significantly more toxic than other components, two levels may be included in the tolerance expression.

(2) **Significant metabolites of concern and tolerance expression.** (i) Using the results of plant and animal metabolism studies, EPA determines which metabolites are of concern and need to be included in the tolerance expression. In each case, this decision is based on the toxicity of the metabolite and the magnitude of its residue. Metabolites that are toxicologically significant and occur at significant levels require a suitable analytical method.

(ii) In some cases, tolerances may be based on only a portion of the residue of concern in order to ease enforcement or to harmonize with international tolerances. This may be referred to as an indicator compound, which typically would be the parent pesticide. However, residue data are still required on all residues of concern so the latter can be included in dietary risk assessment.

(c) **Proposed tolerances—section F of a petition).** (1) Tolerances should be proposed in terms that best represent the TTRs on the raw agricultural commodity, whether it be the parent pesticide, altered forms of it, or both. The proposed tolerance should not be based on an average residue value but should be large enough to include any residue values that could be reasonably expected based on the available data.

(2) The tolerance should not be larger than is needed for the proposed use although some limited accommodation to this rule may be necessary

in the interest of avoiding an inordinate multiplicity of tolerance levels for a single pesticide on a number of different crops. When the analytical method is based on measurement of a common chemical moiety, it will usually determine one or more conversion products along with the parent compound. In such cases, it may be appropriate to propose a combined tolerance for all of the compounds calculated as the parent compound, toxicological considerations permitting.

(3) The petitioner should consider whether the proposed tolerance can be made compatible with maximum residue limits (MRLs) established by the Codex Alimentarius Commission (an organization set up under the auspices of the United Nations to facilitate international trade) or the tolerances established by Mexico or Canada. The tolerance comparison should include compatibility of the numerical level proposed, the residue definition (i.e. the metabolites included in the tolerance), and the commodity definition.

(4) An exemption from the requirement of a tolerance may also be proposed when appropriate (see paragraph (d) of this guideline). When an exemption is proposed, data should be presented to show the level of residues to be expected.

(5) In the case of food additive regulations covering the use of pesticides in food handling establishments, it is contemplated that the regulation may or may not include a numerical tolerance on foods. However, a numerical indication of the expected residue levels is preferred. In either case, the proposed regulation should specify the conditions of use of the pesticide. The determination of whether a numerical tolerance is needed will be based on the toxicity of the residue and the level of possible contamination.

(d) **Exemptions from the requirement of a tolerance**—(1) **Active ingredients.** Exemptions from the requirement of a tolerance are appropriate for pesticides for which no enforcement action can be anticipated. Since an exemption from the requirement of a tolerance means that there is no limit on the level of residue that could occur, exemptions are limited to relatively non-toxic pesticides. Examples of active ingredients for which an exemption is appropriate are acetic acid and sulfur. Exemptions from the requirement of a tolerance for an active ingredient should be requested by submission of a petition. Normally, the only information/data needed in such a petition are the data from petition sections A, B, E, F, and G. The normal residue chemistry data requirements in section D will be waived for toxicologically-innocuous active ingredients. An analytical method is rarely needed for enforcement purposes.

(2) **Inert ingredients.** Inert ingredients of pesticide formulations have been determined to be pesticide chemicals within the meaning of the Act and are subject to the Pesticide Amendment (section 408) of the FFDC

Act. A large number of these inert ingredients have been exempted from the requirements of a tolerance (40 CFR 180.1001). Requests to add other adjuvants should be submitted as petitions for exemption or as a letter to the Director, Registration Division, Office of Pesticide Programs. Data requirements for inerts will not ordinarily be as extensive as for active ingredients. However, an analytical method may be required and a basis for estimation of the level of residues likely to result must be provided. Limitations on the use may be imposed in the exemption regulation. Any clearances of the inert ingredient by the FDA as a food or feed additive should be referenced. The amount of residue chemistry data needed for the exemption of an inert ingredient will vary with the nature of the chemical. The minimum information required are a description of the identity of the chemical and the possible uses involved. If the inert ingredient cannot be deemed toxicologically-innocuous, then additional data will be required. In some cases, the full data requirements described for active ingredient tolerances will be required, while in other cases, only an analytical method and residue data for representative crops will be required. The amount of data required will depend on the toxicity of the chemical and the use restrictions imposed.

(e) **Tolerances for foreign uses.** Foreign uses are not subject to registration requirements. However, proposals for tolerances for residues in any imported foods or feeds should be submitted under section 408(e) of the FFDCA. Tolerances proposed in conjunction with requests for domestic registration are submitted under section 408(d) of the Act. Petitions submitted under section 408(e) should contain the same types of information, including sample labelling, and data as those submitted under section 408(d).