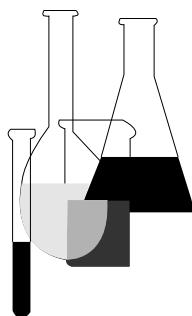




Residue Chemistry Test Guidelines

OPPTS 860.1200 Directions for Use



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 860.1200 Directions for use.

(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 material used in developing this harmonized OPPTS guideline is OPP 171–3 Directions for Use (Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, EPA Report 540/9–82–023, October 1982). The earlier OPP guideline is superseded by this OPPTS guideline. This OPPTS guideline should be used in conjunction with OPPTS guideline 860.1000, Background, which provides general information and overall guidance for the 860 series on Residue Chemistry.

(b) **Purpose.** Directions for use are utilized by the Agency to determine the routes of exposure to pesticides and to determine what types of data are necessary to calculate risk to humans and the environment. In the area of residue chemistry, the directions for use help to determine whether a particular application of a pesticide is a food use or a nonfood use. In general, a food use requires substantial amounts of residue data to establish a tolerance, while a nonfood use needs minimal or no such data. For food uses, the directions for use allow an assessment of whether the residue data reflect the maximum residues likely to occur in foods and animal feeds.

(c) **General.** (1) The directions for use are ordinarily contained in specimen labeling submitted concurrently for registration under FIFRA. Labeling means the actual label affixed to the container together with circulars or leaflets that may accompany it.

(2) It is important that the proposed use be described concisely to facilitate correlation of the proposed use patterns with the method of application used to obtain residue data. The directions should be stated in a manner which is readily understood by the user of the product. Where several products or multiple uses are involved in a petition, it is suggested that Section B of the petition should contain a summary table of all the uses relating to the proposed tolerances. This table should show the crop, dosage range, schedule of applications, formulations to be used, preharvest interval and all other use-relevant use limitations.

(3) All crops (field and/or orchard) which are to be treated with the pesticide formulation should be clearly identified. The crops listed should be consistent with those for which tolerances have been proposed or exemptions requested.

(4) The crop groupings represent exceptions to the foregoing discussion (see 40 CFR 180.41). A tolerance may be proposed for a collection of related crops (crop group) without use directions for each individual crop in the group if the use is the same for each crop in the group. Rep-

representative crops from the crop group may be provided as a minimum requirement for data purposes. However, the use directions for all crops in the group should be similar before a crop group tolerance is established and the specific crops are registered under FIFRA.

(5) The formulation to be used should be expressed quantitatively in terms of its active and inert ingredients. Inert ingredients are defined as all ingredients which are not active ingredients (40 CFR 162.3 (t)) and which may serve various functions.

(6) Paragraphs (d)(1) through (d)(8) of this guideline contain additional points which should be observed in specifying the directions for use in adequate detail.

(d) **Application directions**—(1) **Field and orchard crops.** Application of each formulation should be expressed in terms of pounds active ingredient per acre but may also be given in kilograms of active ingredient per hectare. For band or row treatments, it should be clearly stated whether the pounds per acre rate refers to the area treated or the entire field. In the case of full coverage sprays, as for orchards, the dosage should also be expressed as pounds active ingredient per 100 gallons of spray solution to runoff, because of the large variation in the number of pounds per acre needed for small trees versus large trees. The quantity of pesticide applied per acre for concentrate orchard sprays should also be related to tree size, usually by specifying the same or less active ingredient as that which would be applied using a full coverage spray. In order to lessen the possibility of excess treatment, some options include information on the label which indicates that smaller trees should be treated with smaller volumes of solution and thus less active ingredient per acre. Alternatively, data could be provided to show the maximum likely residues to be expected due to treatment with the most concentrated spray on the smallest mature fruit-bearing tree in commercial production. Additionally, methods of adjusting for tree size as reflected in agricultural practices should be provided. For special modes of application (aircraft, ultra low volume (ULV), mist sprays), the directions for use should include both the spray concentration and the spray volume per acre. The names and quantities of any stickers, spreaders, or other adjuvants used in the spray solution should be given. The maximum number of applications allowed, the minimum interval between application and harvest (preharvest interval (PHI)), and the minimum interval between treatments should be indicated.

(2) **Animal treatments.** Animal treatments present special dosage control problems. The concentration of pesticide in the working solution is the primary consideration in dips and wetting sprays. The directions for dips should include some instructions for recharging and maintaining a constant solution strength in the dip tank, and for the disposal of spent dip solutions. Any factors which may affect the deposition of residues should be covered in the directions for use, e.g. the maximum number

of retreatments, time of the animal in the dip tank, nozzle type, pressure or delivery rate of sprays, and the amount of solution to be applied per animal for pour-on or other specialized treatments. When application of pesticides by automatic devices (i.e. photoelectric or treadle actuated sprays) or backrubbers is proposed, the directions for use should take into consideration such factors as how often they should be recharged and where they are to be placed so that the degree of exposure of the animals may be gauged.

(3) **Fumigants.** (i) Fumigation generally involves the chemical treatment of crops which have been harvested and are being stored or are already in storage. Dosages may be expressed in terms of weight of fumigant per volume of storage space (pounds of active ingredient per 100 ft³) or, where appropriate, weight of fumigant per unit weight of commodity treated (pounds of active ingredient per 1,000 lb grain).

(ii) Parameters such as time of exposure, temperature, pressure, geometry and airtightness of containers, and aeration procedures (including time of aeration) should be specified.

(4) **Aquatic uses.** (i) Aquatic uses include the application of a pesticide to flowing water, impounded water, irrigation ditch banks, dry beds of water conveyance systems, or other aquatic sites.

(ii) The types of application will vary widely, depending on the mode of action of the pesticide. Herbicides for deep-growing submersed weeds may require deposition of slow release granules on the bottom near the root zone. For this type of treatment, the dosage would be expressed in terms of pounds of active ingredient per surface area, much like an agricultural field use. The use of a water-soluble herbicide which acts by direct absorption into the target plant is dependent on maintaining a certain concentration in the water and the dosage should be expressed in terms of parts per million in water. In the latter case, the directions for use should relate the dosage per surface acre to average pond depth.

(iii) Aquatic herbicide applications may require some very specialized equipment. A detailed description of the equipment and principles involved in the treatment should be included—for example, metered pumping of invert emulsions to the bottom of lakes through weighted hoses. A proposed use of timed-release capsules requires information on how the encapsulated material is placed and on the mechanism of the release.

(iv) It is frequently necessary to include limitations on the minimum distance from a potable water or irrigation intake pipe. This limitation is necessary whenever unacceptable pesticide levels occur in water at the intake pipe.

(v) It is sometimes necessary to treat at intervals only portions of impounded water with heavy weed infestations to avoid loss of desirable

species through oxygen depletion. The label should state what proportions of an impoundment should be treated per application and the required interval between treatments. If treatments are intended only for impoundment margins, as opposed to overall broadcast treatment, it should be so indicated.

(vi) Ditchbank treatments are usually made from trucks by boom sprayers. For adequate coverage, there is an unavoidable overlap with some direct addition to the water as well as runoff contamination. The label should clearly direct how such treatments are to be made with minimum contribution of herbicide to the water. A prohibition against cross-ditch spraying may be required.

(5) Foreign uses. (i) Tolerances may be proposed to cover residues resulting on food treated in foreign countries so that such foods may be imported into this country. The pesticide products used in the treatment may be of foreign manufacture, or may be manufactured in the United States and exported to the country where the application is made. Use of a pesticide in a foreign country is not registered under FIFRA. Therefore, section 408 1(d) of the FFDCA, which provides only that registrants under the FIFRA may petition for tolerances, is not applicable. The proponent of a tolerance on imported foods should therefore petition under section 408(e) of the FFDCA.

(ii) For domestic pesticide uses, a determination is made by the Agency that the tolerance is adequate to cover residues likely to result from uses as directed on registered labels. In the case of foreign uses, it is required that the petitioner provide all necessary information on the amount, frequency, and time of application.

(6) Food handling establishments. (i) The potential exists for the contamination of foods due to pesticide treatment of areas where food is prepared or processed. Therefore, the applicant should have clear use directions in order to minimize the contamination of foods. A food additive regulation set under section 409 of the FFDCA specifying the conditions of use in food handling establishments is a requirement for registration of such a use under FIFRA.

(ii) Although directions for use will ordinarily be contained on the product label, the usage directions for those products intended for use solely by professional pest control operators may be presented as a technical bulletin. The potential for food contamination from treatments in areas where food is prepared or processed rests largely upon the care exercised by the applicator in following the directions and observing specified restrictions. For this reason, the instructions should be explicit. The directions for use should include (for example) the type of establishments that may be treated, the dilution instructions for preparing the working solution, the spray concentration, the type of equipment by which it is to be applied,

the mode of application (directed spray to crevices, baseboards, space spray, etc.), dosage limitations including cubic and square foot limitations, frequency of treatment, time of treatment (after-hours in restaurants), and other pertinent information, such as sanitation procedures, removal or covering of food, covering of dishes and utensils, and cleanup procedures before food preparation, processing, or serving resumes.

(7) **Agricultural premises.** Agricultural premise uses will vary widely and might include distribution of granular insecticides to feed lots, fogging of dairy barns, installation of impregnated strips or cords in animal barns, or applications of sugar-based bait sprays to walls, stanchions, and other surfaces of barns. The directions for use should be sufficiently detailed to permit an evaluation of the potential for residues on milking equipment, exposed feeds, drinking and feed troughs, or in meat, milk, poultry, and eggs of animals quartered on treated premises. The directions should state what areas are to be treated, frequency of treatment, whether animals should be removed at time of treatment, and any other pertinent information. Dosage for fogging treatments should be expressed in terms of pounds per unit volume of the structure treated; impregnated strips and similar devices in terms of number of installations per unit volume; sprays in terms of concentration of active ingredient in the solution applied; and feed lot applications in terms of weight of active ingredient per unit area.

(8) **Miscellaneous applications.** The general criteria for use directions do not apply to certain specialized processes, such as the manufacture of impregnated fruit wraps to control fungus diseases, or processes in which pesticides are applied postharvest to fruits, such as in a wax coating. Under these circumstances, the user of the pesticide product is a trained operator experienced in the use of relatively complex mechanical equipment, and directions for use on the retail packages are usually not necessary. However, a complete description of the process including quality control measures and directions for disposal of spent dip solutions or runoff should be made a part of Section B of a petition.

(e) **Restrictions.** (1) Clearly written and practical use restrictions are necessary so that the Agency may gauge the residues likely to result. The following are limitations which should be specified when pertinent to the use:

(i) The maximum number of applications permitted during a growing season together with the timing and the interval between treatments must be given.

(ii) The interval between last application and harvest (or slaughter) should be specified. For plants, this interval is commonly referred to as the PHI. This may be expressed in terms of days before harvest or may be tied to a stage of crop maturity such as **not after first bolls open**. If the directions for use are related to some identifiable growth stage, such

as **first bolls open** or **pegging time**, the petitioner should indicate the minimum time from this stage to harvest. For animal treatments, the interval between the last treatment and slaughter is commonly referred to as the preslaughter interval (PSI) and is usually expressed in days.

(iii) Impractical or unrealistic use restrictions should be avoided. Restrictions against the food or feed uses of plant parts other than the primary raw agricultural commodity are practical only if the item remains under the control of the grower and is not of major economic importance. For example, a restriction against feeding soybean forage is practical because it remains under control of the grower and is of little economic importance. A restriction against feeding dried citrus pulp from a treated grove is not practical or acceptable, since the pulp from a treated fruit would not retain its identity in processing. As another example, a restriction against feeding corn forage or stover (fodder) is impractical because of the major economic importance of corn forage and stover. Restrictions of more than 3 days in the time interval between application to animals and slaughter are normally considered impractical because animals may be sent to slaughter over an extended period of time, and once sold are no longer under control of the user of the pesticide. The table titled *Raw Agricultural and Processed Commodities and Livestock Feeds Derived from Field Crops* in OPPTS 860.1000 may be consulted for an indication of whether a feed item is subject to a feeding restriction on pesticide labels

(2) A restriction calling for discarding of milk during a prolonged interval after the treatment of lactating dairy cattle would be considered unrealistic, since it would impose an economic hardship on the user and would tend to be ignored.

(f) **Specificity of use restrictions.** (i) A restriction such as **Do not use after lay-by** is indefinite in that lay-by time for a given crop may vary considerably due to differences in cultural practices and geographical area. Indefinite terms such as **Do not use on animals being finished for slaughter** should be avoided and a specific withdrawal period should be stated. Similarly, withdrawal times after an animal treatment should be practical. Restrictions should also be as inclusive as possible. For example, the warning **Do not use on dairy animals** is preferable to **Do not use on dairy cows**, if, for example, the intention is to exclude dairy goats.

(ii) In the case of uses in food handling establishments, specific directions to minimize residue transfer are especially important. A general caution such as **Avoid contamination of food** is by itself of limited effectiveness and should be supplemented by explicit warnings such as **Cover food utensils, Do not apply when exposed food is present, Apply after plant operations are shut down, or Wash food contact surfaces before plant resumes operation.**

(g) **References.** Additional source material used in the preparation of this guideline is listed below (items marked with an asterisk are superseded by this guideline).

*(1) Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, Series 171-3; Addendum No. 6 on Data Reporting, Directions for Use, EPA Report 540/09-88-049.

(2) [Reserved]