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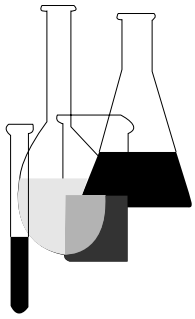
Product Performance Test Guidelines

OPPTS 810.1000 Overview, Definitions, and General Considerations



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 810.1000 Overview, definitions, and general considerations.

(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 materials used in developing this harmonized OPPTS test guideline are OPP guidelines 90–1, 90–2, 90–3, 90–30, and the performance standards in Series 91 through 96 (Pesticide Assessment Guidelines, Subdivision G: Product Performance, EPA report 540/9–82–026, November 1982).

(b) **Overview—product performance**—(1) **General concepts.** (i) The term ''product performance'' refers to all aspects of a product's effectiveness and usefulness. Any evaluation of product performance is conducted in light of expressed and implied labeling claims or recommendations concerning pests, sites, methods of application, application equipment, dosage rates, timing and number of applications, use situations, nature and level of pest control, duration of pest control, compatibility with other chemicals, benefits and/or adverse effects of product use, compatibility of common practices associated with the sites, active ingredient status of chemicals in the formulation, and equipment.

(ii) Initial laboratory, greenhouse, or small plot field testing is conducted to determine the effectiveness of a substance to control or kill specific pest organisms, or to produce desired effects on plants or plant parts, and also to determine whether the substance has sufficient pesticide potential to warrant larger scale testing.

(iii) Effectiveness and usefulness of the proposed product is further proven through advanced large-scale laboratory tests, field tests, in-use tests, or simulated-use tests by procedures which closely approximate actual use and which employ typically-used application equipment.

(iv) All advanced tests must address those factors which would normally be encountered in the use patterns claimed for the product. These factors would depend on the type of pest and site to be treated, and may include: Specificity, degree, and duration of pest control; impact of climate on chemical residuals and bait acceptance; nature and extent of spray coverage; adverse environmental effects such as bioaccumulation (see OPPTS Test Guidelines Series 835 and 840), and toxicity to beneficial nontarget organisms (see OPPTS Test Guidelines Series 850, 870, and 885); increase in population levels of other pests of the target site resulting from control of predatory or competitive microorganisms, or interference with the performance of other pesticides; or any other factors which would establish the safe, effective use of the product.

(v) Except as provided in 40 CFR part 172, an experimental use permit must be obtained to cover test trials involved in use of a pesticide

that is not registered with the Agency and test trials involving a new use of a previously registered pesticide.

(vi) The Agency may require additional information on benefits when a product does not achieve the performance standards, when exorbitant rates are used to achieve the performance standards, or when exceptionally low levels of effectiveness are attained.

(2) **Waiver policy.** The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pests that may pose a threat to human health. Data for termiticides are required because the user cannot determine if they have performed their intended function. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The registrant must develop and maintain the relevant data upon which the determination of efficacy is based. The agency reserves the right to require, on a case-by-case basis (e.g., conditional registrations or benefits data in cases of special reviews), submission of efficacy data for any pesticide product, registered or proposed for registration, when necessary.

(i) Public health uses include the following ones listed and product performance data are, therefore, required to be submitted for these uses.

(A) Uses of antimicrobial agents intended to control pest microorganisms (except bacteria, pathogenic fungi, or viruses living on or in man or other animals) that pose a threat to human health including, but not limited to, microorganisms infectious to man in any area of the inanimate environment. (Also see OPPTS 810.2000, paragraph (b), for additional information on public health considerations.)

(B) Uses of fungicides intended for control of organisms that produce mycotoxins.

(C) Public health uses of invertebrate control agents including, but not limited to, agents intended to control the following: Mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches,fireants, hornets, wasps, poisonous spiders, scorpions, biting midges, centipedes, bedbugs, human lice, and dust mites.

(D) Public health uses of vertebrate control agents including, but not limited to, the; following: Aquatic amphibian and reptilian control agents, terrestrial amphibian and reptilian control agents, avian toxicants, avian repellants, avian frightening agents, bat toxicants and repellants, commensal rodenticides, rodenticides in orchards, rodenticides on farms and rangelands, rodent repellants on cables, rodent fumigants, rodent reproductive inhibitors, mammalian predicides, and domestic dog and cat repellants.

(ii) For those products for which the Administrator will ordinarily waive the requirement for submittal of efficacy test data as indicated in paragraph (b)(2)(ii)(A) of this guideline, the Agency reserves the right and authority to require, on a case-by-case basis, submission of such efficacy data or other test data for any specific product, registered or proposed for registration, whenever the Agency deems that such data are necessary to make proper evaluations for a decision as to acceptability for registration or continued registration.

(A) Conditions under which the Agency may request efficacy data for any product, registered or proposed for registration, include but are not limited to the following:

(*1*) A lack of efficacy has been reported for it.

(*2*) The Agency needs such data to evaluate benefits of the pesticide (or of alternative pesticides) when substantial risks have been identified.

(*3*) The Agency has reason to suspect that the product may not be efficacious.

(B) Thus, the guidelines in this series shall be used by registration applicants as efficacy testing standards in conjunction with label claims and efficacy data reporting requirements.

(3) **How to use OPPTS Test Guidelines Series 810.** (i) Table 1 addresses the organization of the 810 Series. For pesticides which are not antimicrobials, the reader should use paragraph (d) of this guideline, General Considerations for Pesticides Other Than Anti-microbials. OPPTS 810.3000 and 810.4000 contain performance standards and test methods for public health uses of invertebrate and vertebrate control agents, respectively. The actual test procedures will vary according to the characteristics of the chemical, the type of formulation, the target pest, the use patterns, the methods and timing of application, and many other factors. Antimicrobial pesticides are covered in OPPTS 810.2000 which contain both general and specific requirements for these pesticides.

(ii) Identification of explicit methods in these guidelines for all uses is not practical, because an acceptable test for one product or use may not be valid to support another product intended for the same use, or for the same product intended for even a slightly different use. Examples of acceptable methods are provided in specially designated paragraphs of the guidelines, but the applicant or his testing agent must be responsible for the validity of any particular test or tests employed.

(iii) For termiticides and public health pesticides for invertebrate and vertebrate control, the registrant should use additional guidance provided at OPPTS 810.5000 and 810.6000. Table 1 summarizes the organization of the OPPTS Test Guidelines Series 810.

Table 1.—Organization of the 810 Series

Pesticide type	Applicable guideline series	
	General considerations sections	Specific sections
Antimicrobials—Public health	No	810.2000
Rest of Non-public Health Pesticides except termiticides	Yes	None
Termiticides	Yes	810.3000
Public Health except antimicrobials	Yes	810.3000, 810.4000

(4) **Relation of OPPTS Test Guidelines Series 810 to 40 CFR part 158 and to other series of the guidelines.** Relation to 40 CFR part 158, subparts A and B. The registration applicant is referred to 40 CFR Part 158—Data Requirements for Registration for general provisions and policies pertaining to registration data requirements including policy on flexibility in relation to deviation from test standards and acceptable protocols, when tests are required (40 CFR 158.32), and requirements for additional data.

(5) **Relation of OPPTS Test Guidelines Series 810 to OPPTS Test Guidelines Series 850.** The registration applicant is referred to OPPTS Test Guidelines Series 850, Group D: Nontarget Plants, for data guidance on pesticides that contact plants through direct application or through movement of pesticides in the environment, and submission of data on adverse phytotoxic effects to nontarget plants both within the target area and outside the target area.

(c) **Definitions.** The following definitions apply to this guideline.

Effective dosage range or EDR refers to the range of dosage levels beginning with the lowest dosage capable of achieving the level of control specified by the applicable performance standard for the least taxing conditions under which it will be used (e.g., pest levels, soil types, water conditions, geographical and climatological conditions, etc.), and ending at the lowest dosage required to achieve the specified level of control under the most taxing conditions under which it will be used.

Effectiveness refers to a product's ability to control the specific target pest or produce the specified plant or animal response when the product is applied in accordance with the label directions, precautions, and limitations of use. The term effectiveness, as used in this guideline, is synonymous with the term efficacy.

Full coverage, as used in common agricultural practice, refers to a volume of spray applied to plants to the point of runoff or drip.

Large scale plot refers to any plot large enough to permit the use of typical commercial application and harvest equipment (when such equipment is needed for pesticide application).

Low volume or LV, as used in common agricultural practice, refers to a total volume of spray applied broadcast as more than 0.5 gal but less than 5.0 gal/acre (more than 1.89 L but less than 18.93 L/ha) or less than a full coverage spray.

Minimum effective dosage or MED refers to the lowest dose level at which the test substance achieves the level of control specified by the applicable performance standard.

Performance data refers to any data pertaining to pesticide effectiveness and usefulness.

Serial application refers to the label recommended use of a pesticide on a site before or after application of another pesticide to that site, such that the presence of one of the pesticides may affect the effectiveness and usefulness of the other.

Ultra low volume or ULV, as used in common agricultural practice, refers to a total volume of 0.5 gal or less per acre (1.89 L or less per hectare) broadcast.

(d) **General considerations for pesticides other than antimicrobials**—(1) **Scope of considerations.** (i) The registration applicant is reminded that certain efficacy data submittal requirements are waived as described generally in paragraphs (b) and (d)(3)(i) of this guideline. Therefore, while the other paragraphs in this guideline provide guidance concerning the methodology of efficacy testing and the content of test reports, they do not independently establish any data submittal requirements.

(ii) The standards contained in this paragraph apply generally to all studies in this guideline (except for antimicrobial agents (OPPTS 810.2000 (b) and (c)), unless another paragraph of this guideline contains a specific standard on the same subject. In such a case, the specific standards in the other paragraphs shall apply to the conduct of that particular study.

(2) **Test standards**—(i) **Personnel.** All testing and evaluation should be done under the direction of personnel who have the education, training, and/or experience to perform the testing and evaluation in accordance with sound scientific experimental procedures. The Agency may require resumes of personnel who have performed, supervised, reviewed, or evaluated the testing.

(ii) **Test substance.** (A) The test substance shall generally be the formulated product.

(B) In addition to or in lieu of data otherwise mentioned by this guideline, the Agency may require, after consultation with the applicant, data derived from testing to be conducted with:

(*1*) An analytically pure grade of an active ingredient with or without radioactive tagging.

(*2*) The technical grade of an active ingredient.

(*3*) The representative technical grade of an active ingredient.

(*4*) The inert ingredient of a pesticide formulation.

(*5*) A contaminant or impurity of an active or inert ingredient.

(*6*) A plant or animal metabolite or degradation product of an active or inert ingredient.

(*7*) The end-use pesticide product.

(*8*) The end-use pesticide product plus any recommended vehicles and adjuvants.

(*9*) Any additional substance which could act as a synergist to the product for which registration is sought.

(*10*) Any combination of substances mentioned in paragraph (d)(2)(ii)(B) of this guideline.

(iii) **Dosage rates.** (A) The test substance should be tested at various dosage levels including the dosage rates associated with the proposed use. Dosage rates should be tested as requested by each paragraph when applicable. Special attention should be paid to treatment rates on food crops in relation to the tolerance or proposed tolerance. For public health pesticides and termiticides, additional guidance on selection of test dosage rates may be found in the specific discipline paragraphs of this guideline.

(B) The test program (sum total of preliminary and final stage tests) should establish clearly the EDR or the MED as appropriate for the uses involved. The development of an EDR, rather than a single MED, is encouraged, whenever feasible and practical, because the EDR permits at least some of the users the opportunity to use rates other than the maximum rate needed to cover all use situations.

(iv) **Serial applications.** The label use directions may specifically direct serial applications of different products, such as when tank mixing is impractical. These directions should be supported by tests designed to compare the effectiveness and usefulness of application of each product alone with applications of the products applied serially. Special emphasis should be directed toward determining whether or not a minimum time interval between applications of the respective chemicals is warranted.

(v) **Package mixtures.** These products contain more than one active ingredient. Data are needed to establish the efficacy of each active ingredient in a package mixture. However, since it is the efficacy of the formu-

lated product/use-pattern combination that is to be established, testing as part of an experimental use permit program is usually conducted with the package mixture only. In many instances one or more of the separate active components will have been previously registered as a single-component product. In such cases, these data may be included as part of the data base for the package mixture when suitable comparability data have been developed to demonstrate that each active ingredient is effective and safe to use on the target site regardless of whether it is used alone or in the package mixture. (Note: Package mixtures which result in a significant amount of inappropriate or unnecessary usage (dosages, certain active ingredients, inappropriate timing, and unnecessarily high number of applications) of one or more of the active ingredients are not acceptable.)

(vi) **Tank mixes.** Product labeling which implies or recommends mixing products in the spray tank before application should have acceptable supporting data as described below.

(A) Directions for tank mixing of products should be supported by performance data on each component (of the proposed mixture) tested separately as well as data on the mixture used at the dosage rate(s) specified for each pest indicated. The combined minimum and combined maximum dosage rates of each product in the tank mixture should be tested. Guidance pertaining to tank mixtures for environmental fate data appear in OPPTS 835.6400.

(B) The components of a pesticide tank mixture should be physically and chemically compatible. Evaluations of physical compatibility should be conducted using maximum rates of each component in minimum recommended volumes of diluent per acre or hectare, demonstrating effects of order-of-component-addition to the tank, and evaluating effects of water hardness, pH, and temperature on separation, suspendability, and sprayability. Where compatibility is questionable from static tests, actual testing should be done which should employ constant agitation of the mixture as in most commercial field sprayers. (Note: Tank mixes which result in a significant amount of inappropriate or unnecessary usage (dosages, certain active ingredients, inappropriate timing, and unnecessarily high number of applications) of one or more of the active ingredients are not acceptable.)

(vii) **Adjuvants.** Products with labeling which allows or recommends the additions of separately packaged adjuvants to the spray tank should be supported with data indicating their benefits (if claimed) and any detrimental effects (such as increased crop phytotoxicity) which may result from their addition to the herbicide, plant regulator, desiccant, or defoliant. The only adjuvants actually permitted for use with a pesticide will be those adjuvant brand names or defined adjuvant classes specifically named on the pesticide label. The adjuvant rate or range of rates should be indicated on the pesticide label, and should be supported with data on efficacy and

any detrimental effects. If a range of adjuvant rates is recommended, the maximum and minimum rates within that range should be evaluated in conjunction with the intended pesticide product.

(viii) **Geographic distribution of tests.** Pesticide products marketed on a nationwide basis may be used under a wide variety of conditions. The pesticide should be tested in each major geographic area where the pest is known to exist and be of importance, or where the crop is grown in significant acreage. When a pest control program is intended for only one locality where the pest is known to exist in significant amounts, test data from that locality are usually sufficient. For public health pesticides and termiticides, further instructions regarding testing in various geographic areas are located in the individual paragraph series on efficacy.

(ix) **Test design and statistical procedures**—(A) **General test design.** Sound statistical designs and procedures are necessary to assure that valid and appropriate statistical analyses of the data can be performed and that any observed statistically significant differences are attributable to the respective pesticide treatments, and that such pesticide treatments provide the expected pest organism response. Direct comparison of group means of treated sites and untreated control sites is usually sufficient for evaluating treatment effects. The test results, however, for termiticides and public health pesticides should show more than just statistically significant differences between treated and control sites: The differences should generally be of a magnitude which meets or exceeds the performance standards described in each of the subsequent paragraphs of this guideline. (See paragraph (d)(3) of this guideline for more information on performance standards.) For useful references on test design and statistical procedures, see paragraphs (e)(1) through (e)(7) of this guideline.

(B) **Multiple site and pest target combinations.** When more than one pest or site is involved in pesticide applications, separate tests are usually necessary to evaluate product performance against each kind of pest or each kind of plant under each set of variables or use conditions. For vertebrate control agents, however, it is preferred that efficacy be evaluated on one pest species at a time. If more than one method of application is to be employed (such as, for example, air and ground sprays, drenches and injections, or impregnation and surface coating), experiments should be designed to obtain the required data for each method, on or in the same experimental sites, and if separate evaluations can be made, their respective levels of control can be assessed during the test.

(C) **Replicates.** Generally, the number of replicates necessary to demonstrate treatment differences will depend upon several factors, such as variability of test organisms and materials (crops, pests, application equipment, soil conditions), magnitude of treatment effects, and the desired statistical confidence level.

(D) **Sampling procedures.** Sampling procedures should assure that all of the characteristics of the test population to be measured are represented in the samples. The size and number of samples necessary for reliable estimates will vary mainly with the level and uniformity of the organism or the effect to be measured as well as the size and precision of available equipment. For example, entire replicates may need to be harvested to make accurate yield estimates or to measure plant growth responses when low pest populations are present, while representative portions of each plot will probably be sufficient for measuring high density pest populations.

(E) **Considerations for crop test designs.** In designing the test, all variables, both uncontrollable (such as soil texture and microclimate) and controllable (such as irrigation, cultivation, pruning, fertilization, cultivar, and test product application) should be considered. Care should be taken to duplicate carefully all controllable variables (other than test product application) on all treated and untreated plots.

(*1*) **Plot sizes.** Plots should be large enough to reflect actual use conditions and to allow representative application techniques, which may include commercial application equipment. Small plots, such as a single 10-ft (3.3 m) row of vegetable and forage crops, and single-branch or single-tree plots of fruits, are ordinarily insufficient to support valid conclusions about product performance. Factors such as the crop grown, equipment used, expected incidence of the pest, need for residue samples, yield data, and quality studies should be considered in selecting the size of field plots. The plots should be located within a field so as to be representative of conditions throughout the field. Areas of fields such as borders and atypical wet or dry locations must generally be avoided, unless these are the optimum areas for pest damage. For public health pesticides and termiticides, more specific guidance as to adequate test plot sizes is provided in the guidelines on specific pesticide types.

(*2*) **Crops or sites treated.** A representative number of the major cultivars of crops should be represented in the tests. Cultivars should be more extensively utilized as a test variable to demonstrate adverse responses in tests.

(*3*) **Climatic factors.** The testing schedule should be designed to permit evaluation of the effectiveness of pesticides applied under different environmental conditions such as low versus moderate and high precipitation, cool and cloudy versus normally hot and sunny conditions, and low versus high humidity and dew formation, as appropriate to the product use.

(*4*) **Edaphic (soil) and other substrate factors.** The effectiveness of a pesticide product can often be influenced by the type of substrate to which it is applied. Therefore, testing procedures should be designed

to evaluate product performance on those surfaces or substrates intended for treatment. A number of variables relating to soil, such as soil temperature, texture, fertility, pH, organic matter content, moisture content, tillage practices, irrigation, and crop rotation schedules, measurably influence performance of soil-applied pesticides. Accordingly, field tests should be designed, as appropriate, to assess the potential effects of the pertinent variables. Data to determine safety to crops planted in the treated area the same season and in following seasons should be submitted. (See OPPTS 850.1950, 850.2500, 850.4025 (Ecological Effects Test Guidelines).

(*5*) **Spray volume.** The volume of spray is another important variable affecting the performance of pesticides because it directly relates to the distribution and coverage obtained on the target site. When appropriate, testing procedures must be designed to determine the acceptable range of spray volume to be used with the intended application equipment. Special emphasis should be placed on obtaining data on the minimum and maximum spray volumes when a specific amount of product is intended for use in a range of spray gallonages.

(*6*) **Timing of applications.** Test reports should specify the time at which treatment was begun, duration of exposure (if applicable), and intervals between succeeding applications. For example, data on crop treatments should include the following information (when applicable) in relation to timing of applications:

(*i*) Dates of treatments and harvest.

(*ii*) Treatment time in relation to number of days before or after planting, plant emergence, or harvest.

(*iii*) The stage of growth of the crop when treatment was made.

(*iv*) The stage of growth or expected appearance of the pest at treatment time.

(*v*) Duration of exposure to pesticide treatment.

(*vi*) Treatment-to-observation intervals.

(*7*) **Seasons.** For pesticides used outdoors where variations in climatological conditions alter efficacy, the seasons during which the tests were conducted shall be reported.

(3) **Suggested performance standards.** (i) When efficacy data submissions are not waived, performance standards will represent the levels of a product performance that are exhibited by pesticides on specific site/pest combinations and considered acceptable for registration purposes. These standards, however, are not always absolute or inflexible. Labeling statements are based on the performance standards and utilize tests in OPPTS Test Guidelines Series 810.

(ii) Suggested performance standards are usually expressed as percentages of pest control, or percentages of other intended responses, calculated from measurements made on treated plots compared with those made on untreated control plots. Reliance only on untreated control plots, however, is not always sufficient or appropriate, particularly when testing on very large areas against mobile pests, when testing dog repellents, or when conducting tests in mobile substrates, e.g., herbicides applied to moving bodies of water. In such cases, a product may be tested against some other base, such as against another formulation or chemical of known efficacy, or by comparison to pest levels or damage measured before and after the test. For most pest control patterns, efficacy data should be obtained under a full range of pest severity conditions, with particular emphasis on the maximum pest severity likely to be encountered by users.

(4) **Adverse effects.** To the extent possible, efficacy tests should be designed to evaluate possible adverse effects resulting from use of the pesticide. The following are examples of adverse effects which should be considered:

(i) **Phytotoxicity.** Details of data submitted on phytotoxicity are provided in OPPTS Test Guidelines Series 850, Group D (Ecological Effects—Nontarget Plants), but the following explanation may serve as an introduction for those persons developing product performance data. A good test design providing for dosages higher than necessary for pest control on plants will allow an estimate of the adequacy of the margin of safety between effective pesticide levels and those which may injure the plants intended to be protected. Phytotoxicity is usually measured in terms of chlorosis, malformed plant parts, leaf burning, plant wilting, stunting (reduced height), reduced stand, and death. For certain uses, some injury can be tolerated (depending upon the reversibility of effects, or on economic or aesthetic factors), but all injuries should be evaluated and reported. Accordingly, the lack of observable phytotoxic effects should also be reported.

(ii) **Effects on quality of commodities and inanimate objects.** Test programs should be designed to evaluate adverse pesticide effects on treated commodities and surfaces, such as discolored and weakened fabrics, deteriorated food quality, decrease in wool quality, milk production, and unsightly residues on plant foliage. Taste panel tests, color determinations, blemish counts, livestock palatability trials, or other similar measures, should be considered for incorporation into the test program, depending upon the end use of the commodity.

(iii) **Yields and other effects.** Such determinations will aid in advanced planning in the test design. Pesticide treatments may decrease yield, reduce crop quality, or so alter the normal ripening or maturing process that economic problems arise in harvesting. Data should address the absence or the extent to which such effects occur.

(iv) **Effects on wildlife and aquatic organisms.** Refer to OPPTS Test Guidelines Series 850, Groups A and B (Ecological Effects—Aquatic Fauna and Terrestrial Wildlife), for test requirements to evaluate adverse effects on wildlife and aquatic organisms. Observations and evaluation of efficacy test results should include relevant information about possible increase in harmful nontarget organisms as a result of the pesticide use and application, as well as possible increase in beneficial organisms to intolerable levels, and possible adverse effects of presence of pesticides.

(5) **Test descriptions and data reporting**—(i) **Extent of report.** Systematic and complete descriptions of the tests employed and accurate reporting of data derived from laboratory tests and field tests to support label claims for performance of a product or mixture may be essential for proper Agency review and evaluation. Both English and metric units should be given for all rates and measurements for laboratory tests; English units alone are sufficient for field data, but both measurements may be supplied. Application rates expressed as parts per million (ppm) must indicate the basis (weight/weight (w/w) or weight/volume (w/v)).

(ii) **Assembly of report.** Considerations for assembling the reported efficacy data to expedite Agency review of the detailed report include:

(A) **An index of the test reports.** The index should be arranged primarily according to the general types of performance data and secondarily by the site/pest combinations on the label. Additional guidelines based on methods of application, soil textures, geographic areas, or other pertinent variables are encouraged wherever it is feasible and will facilitate an evaluation of the data. It is recommended that numbered tabs be used to identify the individual test reports.

(B) **Tabular summaries of the data.** It is recommended that each horizontal line (or series of several lines) be equivalent to a test, and that columns reflect the major test variables being reported, such as those details listed in paragraph (d)(5)(iii) of this guideline. These summaries should be organized primarily according to site/pest combinations and secondarily according to pertinent variables, such as methods of application, soil textures, or test locations. The purpose of summary tables is to present a condensed and simplified overview of the scope of the test program and the level of product performance obtained. In order to achieve maximum utilization of space in tables, the use of abbreviations, acronyms, or defined codes as well as the grouping of several types of information within columns is encouraged.

(C) **Summarized conclusions related to label claims.** Data analyses and evaluations should be included.

(iii) **Details of report.** All details of the tests should be reported, giving particular emphasis to variables that relate to the label directions, limitations, and precautions. Such details may include:

(A) **Personnel data.** Names, positions, and addresses of persons who conducted and supervised the tests should be reported. Names of all persons who recorded or generated data for the tests should be made part of the record (not submitted but held as records) along with the dates when the items of data were recorded.

(B) **Test substance.** (*1*) Identification should be made of the test substance, including chemical name, molecular structure, and qualitative and quantitative description of its chemical composition as required by OPPTS Test Guidelines Series 830.

(*2*) Manufacturer and lot sample numbers of the test substance should be reported.

(*3*) Type of formulation and content (percent and, for liquids, pounds per gallon or kilograms per liter) of active ingredients should be reported. When a product is diluted before or during application, the report should specify the quantities and identification of each diluent.

(*4*) For many pesticide products, data on similar formulations may be used to supplement data on the specific formulation when the comparability of the formulations has been demonstrated. This procedure is not acceptable, however, for vertebrate control agents because very slight differences in formulation may cause marked differences in efficacy due, principally, to the highly developed sensory perception of many vertebrate pests.

(C) **Testing period.** Report dates during which each test was conducted.

(D) **Method of application.** The methods and types of pesticide placement, such as surface, subsurface (as in soils), or incorporated, shall be reported. Descriptions of surface placements should indicate the method of application, such as wiping, soaking, mopping, dusting, painting, spraying, trail-building, broadcast seeding, or scoop placement.

(*1*) If the surface is to be sprayed, details on spray volume, such as ULV, LV, concentrate, or conventional full coverage spray, should be given in terms of volume per unit area.

(*2*) For subsurface methods, descriptions should indicate whether done by furrow placement, side-dressing, injection, or burrowbuilding. When describing injection methods, such information as spacing, number, and arrangement of chisels with respect to the row and depth of injection should be given.

(*3*) Descriptions of incorporated methods of application should indicate whether done by mixing, drenching, or impregnating. Details on the methods and equipment used and depth of incorporation may be requested for agricultural applications to soils.

(*4*) Information detailing the type of application, such as row (furrow placement, band, or side-dressing) or broadcast, bait boxes, swath placement, pressure-treated, or soaked, should accompany the test report data. Pesticides applied as row or band treatments should specify the band width and the amount of material used per unit of linear row distance, and the amount of material per acre (or hectare) and the row spacing. When per acre (hectare) figures are included in test reports for row or band treatments, the report should specify whether these figures represent the ''actual'' amounts of pesticides applied or the ''broadcast equivalent'' rates.

(E) **Equipment.** (*1*) The types of equipment used should be reported. This may include such items as mistblowers, cyclone seeders, hydraulic ground sprayers, artificial perches, dusters, burrow builders, soil injectors or incorporators, aircraft systems (specify whether fixed wing or helicopter), metering devices, smoke generators, rodent guns, impregnators, and aerosol dispensers.

(*2*) For mistblower applications, information on spray volume, air velocity, swath width, distance from nozzles to the target, and angle of air flow from the vertical should be given.

(*3*) For pesticide application through irrigation systems, the information includes: The types of systems used, such as sprinkler (stationary or mobile), furrow, drip, or flood; the quantity of water applied; description of the pesticide metering devices; pesticide concentrations in water samples collected at various points throughout the system; and any spatial arrangement of crops (if applicable).

(*4*) When pesticides are to be mechanically incorporated into soil, information should be reported on the equipment used, speed and depth of operation, number of passes over the treated area, and intervals between repeated incorporations (if applicable). Sufficient information on mechanical incorporations into soils or other growth media used at sites other than fields may be needed.

(F) **Dosage rate.** (*1*) The dosage rate expressed as active ingredient and formulated product should be reported. Dosages should be reported in terms similar to the following: Amounts per unit of surface area, per unit volume of solvent or diluent, per unit volume or weight of commodity, per unit volume of space, per unit area and depth (acre-foot or hectare-meter), per linear distance of crop row, per animal, per unit weight of animals, and the length of time of spraying and the distance from the target surface (as for certain pressurized products).

(*2*) When other pesticides are applied in the test area, the rates of application for each product, the identification of pesticides used, and the timing of application should be reported.

(*3*) Spray volumes should be included in the data reports.

(G) **Description of application site.** (*1*) The site of application should be reported.

(*2*) The following information should be taken into consideration in describing the sites. Contact pesticides are applied to the pests themselves or to plant parts for which plant regulator, desiccant, or defoliant activity is intended. Residual pesticides are applied to substrates or surfaces which will in turn be contacted by pests. The specific site of application required for effective use of residual pesticides may be related to feeding or behavioral habits of insects and animals, characteristics of plants, mode-of-action of the pesticide, or the location of infection sites of plant pathogenic fungi and bacteria. For example, dogs establish urinary scent posts, and certain repellents should be applied to these areas to be effective; or, as another example, since mites feed principally on the undersides of plant leaves, nonsystemic miticides should be applied to both surfaces to control those feeding and those crawling around. The site of application may also be directly related to the mode-of-action of the pesticide. A systemic insecticide may, for example, be applied to foliage or the root system so it can be transported to various parts of the plant where it will kill or repel feeding insects. A plant regulator may be sprayed on the foliage and cause the desired response at parts of the plant that were not directly sprayed. A herbicide may be applied to the soil, be absorbed by the roots, and be translocated through the stem to the foliage where it exerts its pesticidal action.

(*3*) Texture of soil and its organic matter content should be reported if applicable to the pesticide usage. In situations where pesticides are intended to act through soil or in burrows, conditions such as tilth, compaction, drainage, moisture, mineral content, temperature, and pH should be reported.

(*4*) Dimensions of test plots or sites and number of replicates should be reported. The type of experimental design used such as detailed description and diagram of the experimental test area should be reported.

(*5*) Number and length of crop rows, row spacing, and plant spacing within rows, if applicable, should be reported.

(*6*) If crops or crop sites are treated, a statement regarding cultivar name and other distinguishing characteristics (e.g., level of pest susceptibility) should be reported.

(*7*) When buildings are treated with pesticides, the number of rooms, their dimensions, and their spatial arrangements should be reported.

(H) **Geographic areas.** Geographic areas (state, county, and town) where the tests were conducted, and the rationales for selection of these sites, should be reported.

(I) **Climatic factors.** Critical environmental conditions at application time, such as precipitation, temperature, sunlight, humidity, and wind velocity, should be reported. Abnormal climatic conditions may occur within a given area which cannot be considered in the test design but these may markedly affect results. Such conditions and effects observed should be reported in the discussion or conclusions.

(J) **Pest populations and crop stage.** Target pest population levels at the beginning of treatment, at periodic intervals after treatment, and at the end of the test period should be reported when applicable. The growth stages of the pests and host plants should be reported. Crop growth stage should be referenced to the number of days before or after planting, emergence, or specific development stage or to its height. Whenever possible, the general level of the pest problem being tested should be characterized (light, moderate, severe, or similar phraseology).

(K) **Cultural practices.** When applicable, information is needed on cultural practices that may affect pesticide application to crops because of their impact on product performance. Where applicable, the report must include information on seedbed preparation, seed planting depth, cultivation practices, and supplemental irrigation. Additional details on irrigation practices as an experimental variable are discussed in paragraph (d)(5)(iii)(E)(*3*) of this guideline.

(L) **Observation times.** The interval between treatments and observations for pest control should be reported. Observations for efficacy and adverse effects should be made at intervals which indicate minimum response times and duration of effects. Dates observed and percent control of specific pests or plant responses to growth regulators, desiccants, or defoliants compared to untreated controls and to commercial pesticides (if used as standards) should be reported.

(M) **Unusual events.** Pertinent comments regarding effects test conditions on performance should be reported, particularly when they adversely affect the level of product performance or would invalidate the test data obtained.

(N) **Mode of pesticide entry, movement, and action.** A description of the mode of action and movement of the pesticide (e.g., translocation, tenacity, redistribution through rain) should be included in the test report or referenced when known. For a pesticide used to control vertebrate animals, the report should note how the pesticide enters the pest organism, such as by body contact, inhalation, oral ingestion, or by any combination of these routes.

(O) **Statistical procedures.** A description of the statistical procedures used in the test design and analysis should be reported.

(iv) **Performance evaluations.** (A) A special section of the test report should be devoted to product performance evaluations. The following are examples of systems that may be used to evaluate the submitted data:

(*1*) A rating scale (or percent) showing performance related to efficacy and commercial acceptability as a rating score. Descriptive criteria for each numerical value if a rating scale should be presented.

(*2*) Dose-response data for all site/pest combinations for which registration is proposed.

(*3*) Clearly defined statements of benefits, such as increased yields, unblemished fruits, reduction in nuisance pest levels, reduced disease incidence, fewer rat bites, to be derived from the pesticide use. The applicant should indicate what he considers to be a commercially acceptable level of pest control.

(B) Refer to OPPTS Test Guidelines Series 850, Groups D and E (Ecological Effects—Nontarget Plants and Toxicity to Microorganisms), for reporting phytotoxicity. Report other adverse effects such as spotting of paint, weakening of cloth or fibers, presence or odors of dead pest organisms, secondary poisoning, increase of nontarget species to intolerable levels, and similar adverse or undesirable results.

(6) **Supporting statements.** An applicant may submit written statements of opinion regarding the efficacy and limitations of a particular product, when expressed by individuals reasonably expert in observation and having experience with repeated use of such products. Evidence of the expert's experience should accompany such statements. Testimonials or letters of recommendations from individuals with less than the qualifications described in this paragraph are not acceptable as support for effectiveness claims.

(e) **References.** The following references may be consulted for information on statistical design and analysis.

(1) Dowdy, Shirley and Stanley Wearden. 1991. Statistics for Research. 2nd ed. John Wiley & Sons; NY, NY.

(2) Draper, N.R. and H. Smith. 1981. Applied Regression Analysis. 2nd ed. John Wiley & Sons; NY, NY.

(3) Frank, Harry and Steven C. Althoen. 1994. Statistics: Concepts and Applications. Cambridge Universityi Press; NY, NY.

(4) Gomez, Kwanchai A. and Arturo A. Gomez. 1984. Statistical Procedures for Agricultural Research. 2nd ed. John Wiley & Sons; NY, NY.

(5) Hamburg, Morris and Peg Young. 1984. Statistical Analysis for Decision Making. 6th ed. Harcourt Brace; NY, NY.

(6) Mason, Robert L., Richard F. Gunst, James L. Hess. 1989. Statistical Design and Analysis of Experiments. John Wiley & Sons; NY, NY.

(7) Steel, Robert G.D. and James H. Torrie. 1980. Principles and Procedures of Statistics. 2nd ed. McGraw-Hill; NY, NY.