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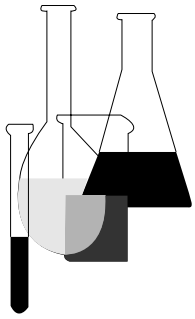
Product Performance Test Guidelines

OPPTS 810.3200 Livestock, Poultry, Fur- and Wool-Bearing Animal Treatments



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 810.3200 Livestock, poultry, fur- and wool-bearing animal treatments.

(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 95–8 Livestock, poultry, fur and wool bearing animal treatments and 95–30 Acceptable methods (Pesticide Assessment Guidelines, Subdivision G: Product Performance, EPA report 540/9–82–026, October 1982).

(b) **Overview.** This guideline concerns efficacy testing of invertebrate control pesticides used on cattle, horses, sheep, goats, swine, chicken, turkeys, other domestic fowls, and fur-bearing animals, such as mink and rabbits, for control of the major arthropod pests that parasitize these animals, and are additionally considered to be public health pests. See OPPTS 810.7000 for a definition of public health invertebrates.

(c) **General considerations**—(1) **Site selection.** Pests of livestock, poultry, fur- and wool-bearing animals include, but are not limited to, nose bot, sheep ked, various biting flies (horn fly and stable fly), ticks, housefly, face fly, and mosquitoes. Evaluating an insecticide that is to be applied directly to such animals to control these pests should generally be based on adequate tests on representative animals from herds or flocks in at least 5 widely-separated regions where the insecticide is to be marketed, unless applicability so limits use of the pesticide in special representative regions. Tests on dairy cattle may not be necessary if comparable to efficacy data are reported from tests using beef cattle.

(2) **Sample size.** Sample size should be representative of the number of animals in a particular treatment group, which can range from one to a herd or flock of thousands.

(3) **Number of trials.** A minimum of 5 large-scale geographically-separated trials are generally necessary, but the number of trials can vary somewhat due to the accessibility of infestations, fluctuations in pest population pressures, behavior, and other important considerations in the biology of the target pest.

(4) **Dosage selection.** Dosage levels and concentrations should be identified in the laboratory or small-scale tests before field testing. The data should include support of the schedule of repeated applications as indicated in the directions for use of the product.

(5) **Application techniques and equipment**—(i) **Single oral dose.** For insecticides administered orally as drenches, boluses, or in capsules, care should be taken that animals receive the entire dose. Record the formulation, final concentration of active ingredient, total amount adminis-

tered, and dosage in terms of mg of active ingredient per kg of body weight of animal. The regulation of many internal applications comes under the authority of the Food and Drug Administration, Bureau of Veterinary Medicine. Some of these pesticides may fall into this category.

(ii) **Feed treatment.** Insecticides administered to animals as part of a feeding regimen should be mixed into the entire feed ration or fed in a small amount of feed which, when consumed, is followed by untreated feed. Record the formulation, final percent content of active ingredient (ppm in feed), or total mg of active ingredient per kg body weight of animal, amount of feed or treatment consumed, and length of treatment period.

(iii) **Water treatment.** Some insecticides may be administered to animals through drinking water. Animals may be treated individually or in groups, which, when having consumed the treated water, are given untreated water. Regardless of the size of the group, the following should be recorded: The formulation, final concentration of active ingredient in terms of ppm in water or mg of active ingredient per kg of body weight of animal, average consumption of water per animal, and duration of treatment.

(iv) **Mineral, salt, or protein supplement.** Insecticides of this type are generally formulated at low concentrations in mineral, salt, or protein supplements and are offered free choice to animals. Because consumption of salt, mineral, and protein supplement varies considerably from animal to animal, it is important to determine whether or not all animals consumed treated materials. Record the formulation, final concentration of active ingredient in terms of percentage or ppm of treated supplement, average consumption per animal per day, dosage in terms of mg active ingredient per kg body weight per day, and length of treatment period.

(v) **Injections.** For insecticides given to animals in the form of intramuscular, intraperitoneal, or subcutaneous injections, record the formulation, amount of material injected per animal, location of injection, and dosage in terms of mg of active ingredient per kg of body weight.

(vi) **Whole-body sprays.** For insecticides applied to animals as whole-body sprays, care should be taken that animals are treated thoroughly and that enough pressure is used to penetrate hair coat and assure wetting of the skin. A variation of the whole-body spray is the use of spray-dip machine to apply spray to animals. With either method, record the formulation, final concentration of active ingredient, equipment used and application techniques, and average volume of spray applied per animal.

(vii) **Dip.** For insecticides used to charge dipping vats, animals should be immersed thoroughly in the dip fluids. Record the formulation, final concentration of active ingredient, volume of liquid in the vat, age of

charge at time of dipping, number of animals dipped, and data on recharging (if necessary). Chemical analyses of active ingredient in vat fluids before and after dipping are necessary to determine the actual amount of active ingredient in the vat fluid.

(viii) **Pour-on treatment.** Insecticides applied to animals by the pour-on technique, ready-to-use formulations, or emulsifiable concentrates diluted with water or oil, are poured down the backline of animals in ounce (milliliter) rates. In an extension of this technique, ready-to-use formulations are applied to a spot on the backline at milliliter rates. Record formulation, diluent, final concentration of active ingredient, amount applied per animal, area treated, and dosage based on mg active ingredient per kg body weight of animal.

(ix) **Dust treatment (livestock).** Insecticides are applied as dusts by power duster or by hand or contained in dust bags and placed in the pasture for free-choice use or placed in openings to feed, mineral, and/or water sources so that animals are forced to use them on a daily basis. With cattle grub control, it is important that dust bags be located so that animals are forced to treat themselves on a daily basis to insure that sufficient insecticide is applied for cattle control. In tests with dust bags for control of ectoparasites, such daily treatment is not essential. Record formulation, final concentration of active ingredient, average amount of dust per animal, location of dust bags, and length of treatment period.

(x) **Back spray.** In tests to control cattle grubs, the animal's backs are sprayed thoroughly with the contact insecticide. Care is taken to force insecticide into the warble openings in the animal's backs. Record formulation, final concentration of active ingredient, equipment used, application techniques, and average volume of spray applied per back.

(xi) **Floor or litter treatment.** Insecticides are applied as mists or fogs, dust, or granules directly to floor areas, litter, or nest areas. Record formulation, final concentration of active ingredient, equipment used, amount of insecticide per square meter of surface treated, and total surface area treated.

(xii) **Dust box treatment (poultry).** Insecticides formulated as dusts or granules are placed into dust box containers and fowl allowed to treat themselves. Record formulation, diluent, final concentration of active ingredient, amount of material per dust box, length of treatment period, number of birds, and average amount of material used per bird during treatment period.

(xiii) **Vapor treatment.** Strands, cords, or other devices impregnated with insecticides are attached underneath or around cages containing infested birds. Insecticides volatilize from the impregnated surfaces and kill ectoparasites on birds. Record the formulation, impregnated material, final concentration of active ingredient, length or weight of impregnated mate-

rial per bird or per cage containing a specific number of birds, and length of treatment period. Low volume or ultra low volume application must be evaluated if these methods are to be specified on the label.

(6) **Record of toxicity and other adverse effects.** Adjusted average daily gains (ADG) on the test and control groups should be recorded and reported. The pesticide product's possible toxic effects on the animal must be evaluated. For example, small amounts of certain solvents cause tolerable minor itching and burning for short periods after application. Higher concentrations may cause death if not diluted before application. The recommended method of treatment for pour-on and other ready-to-use products containing oils should be tested to ensure that the recommended method of treatment will not result in excessive dosages of oil which may evoke adverse reactions in treated animals. The final use dilution of emulsifiable concentrations should be tested to ensure that it does not contain dangerous amounts of oil. Insecticides which are tested for use on livestock, poultry, of fur- or wool-bearing animals should not injure the animal even when application is repeated over a long period of time; the margin of safety to the treated animal is a vital consideration in determining usefulness. Neither should the insecticides appear illegally in or on meat, meat by-products, milk, or eggs. If the treated animal is less than 3 months of age (excluding poultry), the effects of stress caused by a particular operation such as castration, dehorning, or other similar procedures, should be evaluated in conjunction with toxicity data. This is especially important for feed-through insecticides. For other requirements on toxicity, refer to OPPTS guideline series 870, Health Effects Test Guidelines.

(7) **Evaluation and reporting procedures.** The evaluation procedures used should be specified in the presentation of the data. Reports should include formulations, final concentrations of active ingredient in terms of ppm in water or percent active ingredient in dusts, dosage in terms of mg of active ingredient per kg of body weight of animal, length of treatment period, equipment used, and other similar factors. The average daily gain in weight should be reported for any tests of 7 to 14 days duration.

(8) **Untreated controls and comparative treatments.** When it is impractical to maintain untreated control animals, the effectiveness of the test product may be measured by comparative treatments with products of well-known efficacy used as reference standards. To evaluate the effect of treatments, records should be kept on the comparative changes in meat, milk, or egg production or some similar measurement; and insect counts following each treatment. The numbers of animals in the control or comparative treatment groups must be equal to the numbers of animals in a treatment group in small scale tests; in large-scale tests, only a small portion of the animals need to be treated or given a standard treatment. Control groups should contain animals of the same general size, age, condition,

and origin as those in the treatment groups and have similar infestations of parasites or be exposed to similar populations of arthropod parasites.

(d) **Suggested performance standards.** Unless otherwise specified, these standards are presented on the basis of pest population counts from treated compared to untreated animals. All percentages of control refer to the performance of the test product (as determined by insect counts, yield of meat and milk, and any other measures correlated to insect population pressures) against the vulnerable stage(s) of the target pest, when evaluated according to a recognized treatment program under actual field conditions.

(1) **Cattle (beef and dairy)**—(i) **Horn fly.** The percentages of control for the horn fly are based upon pre- and post-treatment counts coupled with a comparison to separate untreated control groups. Such percentages are derived from actual counts of the number of adult flies per side per animal, and may additionally be correlated with average daily weight or milk production.

(A) **Feed treatment, drinking-water treatment, and mineral salt or protein supplements.** A minimum of 90% control of emerging adults along with a 70% reduction of adults on the cattle as measured by side or whole-body counts.

(B) **Whole-body sprays, dips, pour-ons.** A minimum of 90% reduction in infestation.

(C) **Dusts.** A minimum of 95% reduction in infestation.

(D) **Backrubbers.** A minimum of 90% reduction in infestation, under continued use for one month.

(E) **Low volume (LV), ultralow volume (ULV) and waxed-bar applications.** A minimum of 90% reduction in infestation under continued use.

(ii) **Other biting flies: (Stable fly, deer flies, and horse flies).** The percentages of control given for these pests are based upon the feeding rates of flies before treatment compared to the feeding rates of flies on the same cattle after treatment as correlated to the feeding rates on untreated animals taken at the same time. Such feeding rates should be expressed as populations of each separate pest species observed consistently at a particular time of day associated with fly activity.

(A) **Whole-body sprays, dips, pour-on, and dusts.** A minimum of 90% reduction in infestation one day after application and 75% reduction in infestation one week after application.

(B) **Backrubber, LV and ULV applications.** A minimum of 90% reduction in infestation under continued use.

(iii) **Face fly: Whole-body sprays, dips, pour-ons, dusts, backrubbers, LV and ULV applications, smears, baits, ointments, and face wipes.** Reduction in infestation should range from 20-60% for 2-3 days from a single application, based upon a comparison of the numbers of flies per animal pre- and post-treatment correlated with populations of the pest occurring on adjacent untreated herds observed at the same time.

(iv) **Ticks.** The percentage of control listed as suggested performance standards for ticks are based upon pre- and post-treatment counts on the same animals or as the average number counted on untreated controls during the same post-treatment intervals. If pre- and post-treatment counts are utilized as a basis for computing the percentage, then untreated control counts should still be reported to permit correlation with natural tick population dynamics for the site/pest complex.

(A) **Whole-body sprays, dips, pour-ons, and dusts.** A minimum of 90% reduction in infestation one day after application and 75% reduction in infestation for one week after application.

(B) **Backrubber, LV and ULV applications.** A minimum of 90% reduction in infestation under continued use.

(2) **Horses**—(i) **Ticks.** A minimum of 90% reduction in infestation for one week and 75% reduction in infestation for one month, based upon pre- and post-treatment counts in comparison with untreated controls.

(ii) **Flies: Dips, whole-body sprays, fine-mist sprays, toxicants and/or repellents in aerosols, sponge-ons, wipe-ons, smears, baits, and treated halters.** The percentage given as a suggested performance standard for fly control are based upon a reduction in infestation numbers for a minimum period of 3 hours or that period of protection to be claimed on the label, whichever is shorter. A minimum of 90% reduction in infestation under continued use.

(3) **Chickens, turkeys, and other domestic fowl**—(i) **Manure-inhabiting fly larvae**—(A) **Feed treatment.** A minimum of 90% reduction in infestation under continued use, based upon both adult fly reductions determined either by manure emergence or manure bioassay testing, comparing both treated and control groups.

(B) **Fly larvicides to manure.** A minimum of 90% reductions in infestation for period of 2 weeks after treatment, based on the criteria presented in paragraph (d)(3)(i)(A) of this guideline.

(ii) [Reserved]