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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION G

PRODUCT PERFORMANCE

by

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Subseries 91B: NON-PUBLIC HEALTH USES

§ 91-51 General considerations.

(a) Scope. Sections 91-51 through -56 contain information concerning testing and performance of antimicrobial pesticide products for uses which are not directly related to human health. These uses include control of odor-producing bacteria, bacteria causing spoilage, deterioration, or fouling of materials such as paint or industrial fluids, and microorganisms infectious only for animals, where product failure against the specified pests would not have human health consequences. Pursuant to the efficacy data waiver provisions of Section 3(c)(5) of FIFRA, and § 162.18-2 of the FIFRA sec. 3 regulations, efficacy test data for these uses are not generally required to be submitted to support product registration [See § 90-1(b)]. Also, refer to § 101-1(b),(c),(d), and § 101-30 of Subdivision H for additional information concerning the relationship between label claims, human health considerations, and performance requirements for antimicrobial products. Requirements for testing and performance for those uses of antimicrobials which are identified as directly related to human health are provided in §§ 91-1 through 91-8 of this series. Labeling guidance for all uses of antimicrobial pesticides, both health-related and non-health related, are contained in §§ 101-1 through -16 of Subdivision H.

(b) General testing considerations. (1) In-use tests. Generally, demonstration of effectiveness of antimicrobial products in controlling microorganisms which are aesthetically or economically undesirable may be accomplished by establishing a correlation between successful control of the pest problem (e.g., odor, spoilage, fouling) and limitation of numbers of the target microorganisms at the site under actual conditions of use. In-use tests can be considered for any product of this kind on a case-by-case basis. However, field tests under an experimental use permit (refer to Subdivision I) are prescribed as a requirement only for the following non-public health uses:

(i) Antimicrobial fuel additives [see § 91-53(c)].

(ii) Antimicrobial additives for sugar mills [see § 91-53(d)].

(iii) Antimicrobial additives for poultry and livestock drinking water [see § 91-55(a)].

(2) Simulated-use tests. Except for the uses indicated in paragraph (b) of this section, simulated use laboratory tests can usually be considered as acceptable alternatives to actual in-use tests. Simulated-use tests should be designed to include the following basic elements:

(i) Identified test microorganisms (at least to the generic level) associated with the pest problem at specified site(s).

(ii) Appropriate surface(s) or substrate(s) which support growth of the test microorganisms under the environmental conditions (e.g., temperature, relative humidity) which simulate the in-use situation.

(iii) Adequately replicated test systems consisting of material inoculated with the test microorganisms and treated as directed with the antimicrobial product, together with parallel inoculated untreated controls.

(iv) Periodic observations on the presence or absence of the pest problem (e.g., odor, spoilage) which should include chemical, physical, or olfactory measurements.

(v) Parallel quantitative sampling techniques (e.g., agar plate counts) to enumerate the test microorganisms at appropriate intervals.

(vi) Conduct of the tests for a period of time which is recommended or required in actual use.

(3) Tests designed for public health uses. Effectiveness of antimicrobial products for certain uses in controlling microbial pests which are aesthetically undesirable (e.g., odor-causing bacteria) can often be extrapolated from the same kinds of efficacy tests required for public health uses (e.g., disinfectants, sanitizers, residual self-sanitizing treatments; see §§ 91-1 through -8 of this series) except for substitution of appropriate test microorganisms. Efficacy test data must be developed and submitted in accordance with human health uses (see §§ 91-1 through -3 of this series) when effectiveness is claimed or implied in labeling against microorganisms infectious for both man and animals. This is necessary to assure minimal protection of persons in contact with the animal environment. Qualified label claims against animal pathogens only would not generally require submission of specific test data against those microorganisms. When necessary [see § 162.18-2(d)(3)(ii) of the FIFRA sec. 3 regulations], the tests and performance criteria would be the same as those indicated for public health uses (§§ 91-1 through -8) except for substitution of appropriate test microorganisms.

(4) Qualitative screening tests. Qualitative data developed by presumptive screening tests, such as phenol coefficient tests, nutrient broth inhibition tests, or zones of inhibition on seeded agar or streak plates, are not considered to be of value in providing meaningful results that can be associated with end-uses of antimicrobial products and are unacceptable as documentation of efficacy for end-use claims. However, qualitative tests of this kind are acceptable to document potential or presumptive value of antimicrobial pesticide products intended only for formulation purposes (see § 91-57].

(5) Test substance. Unless othewise specified, products should be tested on the formulation as offered for sale and in accordance with the proposed directions for use.

(6) Neutralizers. In testing the efficacy of any antimicrobial product, appropriate neutralizers should be employed in the microbiological assay system, and evidence obtained to show that the neutralizers employed

inactivate the active ingredient(s) and do not possess any antimicrobial activity themselves. In lieu of specific evidence of chemical neutralization, it must be documented that appropriate secondary subculturing techniques have been employed that preclude residual effects of active ingredients in the assay medium. [Refer to § 91-30(e)(7).]

(7) Test variations. The protocol for testing will vary according to the type of product, type of substance to be treated, proposed use pattern, label claims, directions for use, and other factors peculiar to the specific product. In many cases, specific recommendations (such as the amount of replication) can be determined only after consideration of these factors. Refer to § 91-30(e) for guidance on some common test modifications (e.g., hard water, organic soil).

§ 91-52 Products for use on hard surfaces.

(a) Disinfectants (animal health). The following apply to all products represented in labeling as disinfectants for animal premises and equipment, including veterinary uses, farm uses, kennels, pet shops, zoos, and household pet areas.

(1) Control of microorganisms infectious for both man and animals: Public health uses. The efficacy data waiver provision § 90-1(b) is not applicable to microorganisms which are infectious for both man and animals. Unless disinfecting, germicidal, or bactericidal claims are specifically qualified as intended against animal and veterinary pathogens only, animal and veterinary premises disinfectants must be supported by basic efficacy data developed and submitted in accordance with the requirements for public health uses.

(i) Test standard. Same as § 91-2(b)(1), (c)(1), (d)(1), or (g)(1) of this series.

(ii) Suggested performance standard. Same as § 91-2(b)(2), (c)(2), (d)(2), or (g)(2) of this series.

(2) Control of microorganisms infectious only for animals: Non-public health uses. The efficacy data waiver provision § 90-1(b) is applicable to microorganisms which are infectious only for animals. However, the efficacy tests appropriate for such supplemental efficacy claims are the same as those which are required for public health uses, except for substitution of specifically claimed animal pathogens as test microorganisms.

(i) Test standard. Same as § 91-2(e)(1), (f)(1), (h)(1), or (i)(1) of this series, using specifically claimed animal pathogens as test microorganisms.

(ii) Suggested performance standard. Same as § 91-2(e)(2), (f)(2), (h)(2), or (i)(2) of this series.

(b) Odor control treatments (non-residual). The following apply to products represented in labeling as non-residual treatments to kill or reduce the number of odor-causing bacteria.

(1) Test standard. Same as § 91-2(b)(1), (c)(1), or (j)(1) of this series, except that pure culture isolates of identified odor-causing bacteria must be employed as test microorganisms.

(2) Suggested performance standard. Same as § 91-2(b)(2) or (c)(2) of this series for claims to kill odor-causing bacteria; same as § 91-2(j)(2) of this series for claims to reduce the number of odor-causing bacteria.

(c) Odor control treatments (residual). The following apply to products represented in labeling as residual treatments to reduce the number of odor-causing bacteria or bacteriostatic odor control in the presence of moisture.

(1) Test standard. Same as § 91-2(m)(1) of this series, except that pure culture isolates of identified odor-causing bacteria must be employed as test microorganisms.

(2) Performance guidance. Same as § 91-2(m)(2) for claims to reduce the number of odor-causing bacteria; for bacteriostatic odor control claims, the numbers of test microorganisms recovered from the treated surfaces should be less than the number recovered from the parallel control surfaces and no greater than the "0-time" control.

§ 91-53 Products for use on fabrics and textiles.

(a) Laundry additives. The following applies to antimicrobial products which bear label recommendations for treatment of laundry for odor control.

(1) Odor control pre-soaking treatments (non-residual). The requirements for products recommend to kill odor-causing bacteria on soiled fabrics by total immersion in the use solution prior to routine laundry operations are as follows:

(i) Test standard. Same as § 91-4(a)(1)(i) of this series, except that pure culture isolates of identified odor-causing bacteria must be employed as test microorganisms.

(ii) Suggested performance standard. Same as § 91-4(a)(1)(ii) of this series.

(2) Odor control laundry additives (non-residual). The following apply to products which bear label claims to kill or reduce the number of odor-causing bacteria when used in automatic or manual washing machine operations are as follows:

(i) Test standard. Same as § 91-4(a)(2)(i) or (a)(3)(i) of this series, except that pure culture isolates of identified odor-causing bacteria must be employed as test microorganisms.

(ii) Suggested performance standard. Same as § 91-4(a)(2)(ii) for claims to kill odor-causing bacteria; same as § 91-4(a)(3)(ii) for claims to reduce the number of odor-causing bacteria.

(3) Odor control laundry additives (residual). The following apply to products which bear label claims as laundry treatments to reduce the number of odor-causing bacteria or provide bacteriostatic odor control on treated fabrics in the presence of moisture when added to washing machine operations are as follows:

(i) Test standard. Same as § 91-4(a)(4)(i) of this series, except that pure culture isolates of identified odor-causing bacteria must be employed as test microorganisms. If claims are made for controlling development of ammonia odors from urine on laundered fabrics, Proteus mirabilis ATCC 9240 is required as the test microorganism and urea 1/ must be added to test swatches.

(ii) Suggested performance standard. Same as § 91-4(a)(4)(ii) of this series for claims to reduce the number of odor-causing bacteria; for bacteriostatic odor control claims, the numbers of test microorganisms recovered from treated swatches should be less than the numbers recovered from the parallel control swatches and no greater than the "0-time" control; and for ammonia control claims, ammonia production should be delayed for the time period claimed.

(b) Carpet treatments. The following apply to products bearing label claims as carpet treatments to reduce the number of odor-causing bacteria.

(1) Test standard. Same as § 91-4(b)(1) of this series, except that pure culture isolates of identified odor-causing bacteria should be employed as test microorganisms.

(2) Suggested performance standard. Same as 91-4(b)(2) of this series.

(c) Mattresses and upholstered furniture. (1) Gases or vapors. The use of gases or vapor is currently the only effective and practical means of treating entire mattresses, upholstered furniture, pillows, and similar objects to kill or reduce the number of odor-causing bacteria. The following apply to products bearing such label recommendations:

(i) Test standard. Same as § 91-4(c)(1) of this series, except that pure culture isolates of identified odor causing bacteria should be employed as test organisms.

1/ See: Latlief, M.A., M.T. Goldsmith, and J.L. Stuart. 1951. Germicidal and sanitizing action of quaternary ammonium compounds on textiles; prevention of ammonia formation from urea by Proteus mirabilis. J. Pediatr. 39: 730-737.

(ii) Suggested performance standard. Same as § 91-2(b)(2) or (c)(2) for claims to kill odor-causing bacteria; same as § 91-2(j)(2) for claims to reduce the number of odor-causing bacteria.

(2) Liquids. The use of liquid products applied by mechanical or pressurized spray for treating mattresses, upholstered furniture, pillows, and similar objects is an effective means of reducing the number of odor-causing bacteria on or in the ticking only. The following apply to products bearing such label recommendations:

(i) Test standard. Same as § 91-2(j)(1) of this series, employing ticking material instead of hard surface carriers as the test and control surfaces, and employing pure culture isolates of identified odor-causing bacteria as test microorganisms.

(ii) Suggested performance standard. Same as § 91-2(j)(2).

(d) Impregnated fabrics and textiles. The following apply to products intended for treatment of fabrics and textile materials, usually during the manufacturing process, to provide durable residual antimicrobial activity for reducing the number of odor-causing bacteria or bacteriostatic odor control on treated surfaces in the presence of moisture.

(1) Test standard. Same as § 91-2(m)(1) of this series, employing treated and untreated fabrics or fabricated items instead of hard surface carriers as the test and control surfaces, and employing pure culture isolates of identified odor-causing bacteria as test microorganisms.

(2) Suggested performance standard. Same as § 91-2(m)(2) of this series, for claims to reduce the number of odor-causing bacteria; for bacteriostatic odor control claims, the numbers of test microorganisms recovered from treated surfaces should be less then the numbers recovered from the parallel control surfaces and no greater than "0-time" control.

§ 91-54 Products for processing and industrial uses.

(a) In-can paint preservatives. Antimicrobial products which bear claims for use as preservatives in paint formulations are pesticides, and should meet the requirements indicated below. Paints containing preservatives are not pesticides unless pesticidal claims are made or implied.

(1) Test standard. Products proposed for use in preserving water-based paints should show effectiveness in controlling spoilage or deterioration caused by bacteria in at least two representative paint formulations in which the product is intended for use. Tests should be carried out in at least three replicates of each of the two paint formulations using pertinent microorganisms and adequate controls. Actual bacterial isolates (identified at least to genus) from spoiled paint and/or ATCC paint spoilage bacteria should be

employed as test inocula. Mixed bacterial and fungal inocula are not acceptable in demonstrating bacterial deterioration. Efficacy data should be derived from simulated-use type tests with quantitative bacteriological sampling and concurrent observations of paint quality. Both test and control samples should be tested for a period of six months to one year. The test protocol, including such elements as frequency of repeated bacterial challenge, is contingent upon the intended preservative use pattern.

(2) Suggested performance standard. The data should show control of bacterial growth and control of bacterial-caused deteriorative (physical and chemical) changes in the treated paints during the test period. The data from control paints should show not only survival of test bacteria, but also significant growth and resultant deteriorative (physical and chemical) changes.

(b) Metalworking fluids. The following apply to products bearing label claims for preservation against bacterial growth and deterioration in metalworking fluids.

(1) Test standard. The product should be tested in one identified representative metalworking fluid formulation for each type (e.g., emulsifiable oil, semi-synthetic fluid, synthetic fluid) in which the product is recommended for use, and at the fluid-to-water ratio recommended in labeling. Three replicate tests should be carried out on each metalworking fluid formulation using appropriate controls. Each metalworking fluid formulation should be inoculated with a minimum of three different test bacteria. Each of the test bacteria should be identified at least to genus level. It should be documented that each of the test bacteria has been isolated from spoiled metalworking fluids of the type(s) in which the prduct will be tested or has been successfully employed to induce spoilage of such fluids in other tests. Either single, pure cultures of bacteria or a mixed bacterial inoculum may be employed. However, a mixed culture inoculum of bacteria and fungi is not acceptable. Although the control of microbial growth in metalworking fluids involves fungi as well as bacteria, fungal growth should be considered as a separate, though related control problem. Refer to §§ 93 (Efficacy of Fungicides and Nematicides) for information regarding the control of fungal growth. Each of the test bacteria should be present in the inoculum at a concentration at least 10^6 viable cells per ml of metalworking fluid. The tests should be carried out at a temperature of 25-28°c for periods of time with dosage amounts and intervals, and with fluid make-up procedures that are consistent with the recommendations for use on the label. Quantitative bacteriological sampling should be conducted with concurrent observations of fluid quality. Reinoculation with the test bacteria at regular intervals (e.g., weekly) to simulate repeated contamination/challenge to the system is necessary. The metalworking fluid in the control should be subjected to the same procedures.

(2) Suggested performance standard. The test should demonstrate control of deteriorative changes and inhibition of bacterial growth in metalworking fluids treated with the proposed product as recommended in labeling. The tests should also demonstrate, in metalworking fluids not treated with the proposed product, not only survival, but significant bacterial growth and resultant deteriorative changes. The results should include a report of

the physical or chemical changes observed in the fluids being tested.

(c) Antimicrobial fuel additives. The following apply to products bearing label claims for control of bacterial growth in kerosene based fuels (including jet aviation fuels) subject to water contamination, and diesel fuels or heating oils stored in metal tanks. With aviation fuel additives, the Federal Aviation Administration (FAA) should be consulted as to the acceptability of the additive from the standpoint of certification for particular airframes or engines.

(1) Test standard. (i) Laboratory test. The following basic elements should be incorporated into a presumptive laboratory test. A microbiological assay using Bushnell-Haas media plus the fuel (the fuel-to-liquid media ratio should be equivalent to that found in the field under actual conditions of use) inoculated with a mixed culture of bacteria and fungi (identified at least to genus) isolated from contaminated fuel and treated at the concentration recommended on the label. These data would presumptively determine the efficacy of a product.

(ii) Field test. (A) Aviation fuel additives. After presumptive efficacy is established as indicated in paragraph (c)(1)(i) of this section, products proposed for use in engines and/or airframes of aircraft should be field-tested according to the requirements specified in FAA Advisory Circular AC 20-24A, dated April 14, 1967, under an experimental use permit issued by the Agency. When an additive has not been certified for use in a particular aircraft engine and/or airframe, a disclaimer for such use must appear on the label.

(B) Other fuel additives. Any other proposed uses (diesel fuels, heating oils) would require field-derived efficacy data under an experimental use permit issued by the Agency after presumptive efficacy is established as indicated in paragraph (c)(1)(i) of this section.

(2) Suggested performance standard. The product should be shown to inhibit microbial growth in the presumptive laboratory test, and control the problems associated with microbial growth in the fuel systems employed in the field test. Federal Aviation Agency certification is required for aviation fuel additives.

(d) Antimicrobial additives for sugar mills. The following apply to products bearing claims for control of bacterial growth in sugar mill processes. Because cane-sugar and beet-sugar mills differ both in plant design and processing procedures, actual in-use testing should be conducted in both types of mills when products are recommended in labeling for use in both types.

(1) Test standard. (i) Laboratory test. Laboratory data showing the effectiveness of the product in inhibiting the growth of or reducing the number of representative Leuconostoc mesenteroides isolated from spoiled cane or beet sugar pressing should be provided.

(ii) Field test. Based on these data and on label recommendations, in-use testing should be conducted in at least one cane-sugar and/or one beet-sugar mill under an experimental use permit to demonstrate the efficacy of the product when used as directed. The basic elements which should be

incorporated in the test protocols generally employed in the sugar mills should include the following: all chemical assays (e.g., Brix, invert sugar, lactic acid); all bacteriological assays based on plate counts, standard dilution methods, or other methods recognized as suitable by the industry (indicating time intervals and points of location in the systems where assay samples were taken); visual or other suitable rating of the control of bacterial slime accretion in the mill system; identification by genus and species if possible) of the isolated microorganism(s) which utilize sucrose; and the control treatment. The control treatment may be substituted with published information providing bacteriological data from untreated or inadequately treated systems, along with comparative bacteriological data from a comparable sugar mill treated with a formulation already registered for this use. Test reports should include, but are not limited to, the following: weight of raw cane or beets processed per unit time; product feed rate and/or concentrations used; the point or points in the mill system of product addition; location(s) and dates of the tests; and names (and titles or positions) of persons conducting the tests. Prospective registrants are reminded that a food-additive regulation or exemption from the requirement of such regulation under the Federal Food, Drug, and Cosmetic Act must be established before a product of this type can be registered.

(2) Suggested performance standard. The laboratory test should show that the product inhibits the growth of Leuconostoc mesenteriodes. The field test data should show the application of product according to label directions permits efficient operation of the mill system by reducing dextran deposits caused by the growth of sucrose-utilizing bacteria (i.e., L. mesenteroides) and that by maintaining the microbial population at an acceptable level, an increase in the yield of sucrose is realized due to the reduction of inversion losses.

(e) Miscellaneous preservative uses. In accordance with § 162.4(a) and (b) of FIFRA sec. 3 regulations, products that are recommended in labeling for use as non-food commodity preservatives are pesticides. Preservatives commonly bear claims to control bacterial spoilage or deterioration in such commodities as paper coatings, adhesives, plastic formulations, ceramic glazes, grouts, floor wax emulsions, gaskets (paper, felt, cork, rubber, vinyl), films and foams of polyvinyl and polyurethane, dextrin-based inks, photographic solutions, laundry starch, and colloidal graphite. Such products should be tested in each commodity claimed to substantiate effectiveness as a perservative. In accordance with § 162.4 (c) of FIFRA sec. 3 regulations, the preserved commodities themselves are exempt from registration.

(1) Test standard. Efficacy data should be derived from simulated-use tests with identified (at least to genus) spoilage bacteria. The tests should be carried out in triplicate using untreated controls with each commodity for a period ranging from several days to a year, depending upon the intended end use. Quantitative bacteriological sampling and concurrent observations of commodity quality should be performed.

(2) Suggested performance standard. For an effective treatment, the results should show inhibition of bacterial growth by quantitative techniques that can be related to colony-forming units with those microorganisms that have been isolated from the specific deteriorated substrate. Deterioration of the substrate in the untreated controls should be demonstrated, and the integrity of the treated substrate should be maintained and protected. The type of spoilage or deterioration which occurs in the untreated substrate should be described and documented.

§ 91-55 Products for control of microbial pests associated with human and animal wastes

(a) Self-contained toilet systems. Since it is ordinarily impractical to disinfect or sanitize human excrement in self-contained toilet systems by treatment with antimicrobial chemicals, the only pesticidal value attributable to such treatment is bacteriostatic odor control. The following apply to products bearing such label claims or recommendations.

(1) Test standard. Controlled in-use or simulated-use studies should be conducted comparing self-contained toilet systems treated with the bacteriostatic chemical with identical systems without the chemical. Quantitative bacteriological assay techniques, which can be related to colony-forming units, should be conducted periodically to evaluate inhibition of growth of the natural microflora contained in the waste of the treated system, when compared with growth in the untreated system. The test and control systems should be subjected to similar usage to provide meaningful data. The test protocol should incorporate a sampling schedule consistent with the time interval over which bacterial growth control is intended. Olfactory determinations comparing the development of odors in the test and control phases of the study should be performed simultaneously with the bacteriological determinations. The test should be conducted with an adequate control on each type of toilet system for which the product is intended for use.

(2) Suggested performance standard. The study should show that the product is effective in preventing the development of offensive odors during the time period that such control is intended. Bacteriological assays should demonstrate the inhibition of growth of microorganisms in the test system.

(b) Toilet bowl and urinal surfaces. The following apply to products bearing label claims to kill or reduce the number of odor-causing bacteria on toilet bowl and urinal surfaces.

(1) Test standard. Same as § 91-2(b)(1)(c)(1) or (j)(1) of this series, except that pure culture isolates of identified odor-causing bacteria should be employed as test microorganisms. Note that the contained bowl water (approximately 3 qts. or 96 fl. oz.) should be taken into consideration in determining the appropriate use dilution to be tested for toilet bowls.

(2) Suggested performance standard. Same as § 91-2(b)(2) or (c)(2) of this series for claims to kill odor-causing bacteria; same as § 91-2(j)(2) of this series for claims to reduce the number of odor-causing bacteria.

(c) Toilet and urinal bowl water. The following apply to products bearing label claims to reduce the number of bacteria or bacteriostatic control for odor, slime, or discoloration in toilet bowl water.

(1) Test standard. Same as § 91-7(b)(1) of this series, except that pure culture isolates of identified odor-, slime-, or discoloration-producing bacteria must be employed as test microorganisms.

(2) Suggested performance standard. Same as § 91-7(b)(2) of this series, for claims to reduce the number of bacteria; for bacteriostatic claims, the numbers of test bacteria recovered from the treated water should be less than the numbers from the parallel control and no greater than the "0-time" control; and for slime, odor or discoloration control claims, such problems should be delayed for the time period claimed.

(d) Bird and animal cage litter treatments. The following apply to products intended for application to or incorporation in pet bird and animal cage litter for bacteriostatic odor control in the presence of urine or wet fecal contamination.

(1) Test standard. Controlled in-use or simulated-use test should be performed to show the following:

(i) Numbers of bacterial contaminants in treated and untreated litter after initial deposition of actual bird and/or animal excrement and at periodic intervals thereafter (including repeated challenges with additional excrement) for the time interval recommended for use of the litter.

(ii) Olfactory assessment of the degree of odor control achieved over the same interval.

(2) Suggested performance standard. The numbers of bacterial contaminants in the treated litter should show a reduction over those in the untreated control, and the development of offensive odors should be reduced or delayed in the treated litter over the time interval claimed.

(e) Treated vomitus absorbents. The following apply to products intended for bacteriostatic odor control during clean-up and disposal of vomitus removed from inanimate surfaces.

(1) Test standard. Controlled in-use or simulated-use tests should be performed to show the following:

(i) Numbers of bacterial contaminants in treated and untreated absorbent after initial deposition of actual vomitus and at periodic intervals thereafter for the time period recommended or claimed for use of the absorbent to control odor.

(ii) Olfactory assessment of the degree of odor control achieved over the same period.

(2) Suggested performance standard. Same as paragraph (d)(2) of this section.

§ 91-56 Products for treating water systems.

(a) Drinking water for poultry and livestock. The purpose of the antimicrobial treatment of poultry and livestock drinking water should be clearly defined in labeling. Treatment of drinking water for the purpose of providing medication for animals, and/or implied claims of disease control, identify the product as a drug, and required approval by the Food and Drug Administration. The standards for products represented in labeling for treatment of poultry or livestock drinking water for pesticidal benefits (disinfection, sanitization, bacteriostasis) are considered below. Such products require a pesticide tolerance from the EPA under the Federal Food, Drug, and Cosmetic Act.

(1) Test standard. (i) Laboratory tests. Presumptive efficacy of poultry and livestock drinking water disinfectants or sanitizers may be established with data derived from the AOAC Method for Water Disinfectants for Swimming Pools (§ 91-30 Recommended method No. 14 in § 91 of this series) or with slight modifications thereof, against Escherichia coli (ATCC 11229) and Streptococcus faecalis (PRD). Presumptive efficacy for chemicals intended to provide bacteriostasis may be substantiated with any of several presumptive microbiological screening tests (e.g., minimal inhibitory concentrations derived from a broth tube-dilution type method, and zones of inhibition derived from a seeded agar cup plate type method).

(2) Field tests. Based on these data, controlled quantitative, microbiological studies should be designed to demonstrate the level of efficacy of the product in poultry or animal drinking water under actual conditions of use. Field-derived data should be developed under an Experimental Use Permit demonstrating the efficacy of the product when used as directed. Test conditions will vary with the level of effectiveness claimed, types of microorganisms to be controlled, application techniques for treating the water, treatment intervals, water dispensing system, type of animal facility, organic load, and other factors related to the proposed use.

(2) Suggested performance standard. The laboratory test should show elimination, reduction, or inhibition (i.e., disinfection, sanitization, bacteriostasis) of the test bacteria. Acceptable results for the field test will depend upon the level of activity claimed for specific use conditions.

(b) Potable water treatment units. Any unit intended for physical and/or chemical treatment of microbiologically potable water from a municipal treatment facility to remove undesirable taste odors, chemicals, or other aesthetically objectionable properties is identified as a potable water treatment unit. A substrate such as activated charcoal (with or

without a bacteriostratic agent) is incorporated into the unit for this terminal processing treatment of potable water prior to consumption. Since the requirements of the Safe Drinking Water Act do permit municipally-treated drinking water to contain a limited number of harmless "saprophytic" bacteria which are commonly recognized contaminants of water, an antimicrobial agent is sometimes incorporated in a potable water treatment unit to provide bacteriostatic activity against these contaminants. Only potable water treatment units containing a bacteriostatic agent are under the purview of the Act.

(1) Test standard. Controlled, simulated-use studies for the potable water treatment unit should be conducted under conditions representing actual use, employing a defined municipally-treated water source. The test design of the study, which will vary for different types of units and patterns of use, should include the following basic elements:

(i) Evidence that the function of the potable water treatment unit (without a bacteriostatic agent) is impaired and/or adversely affected by identified microbial contaminants present in municipally-treated water, resulting in a recognized aesthetic problem (e.g., undesirable tastes or odors);

(ii) Quantitative determination of the level of microbial contamination in the test water before and after passage through the control (without a bacteriostatic agent) and test units;

(iii) Documentation of the bacteriostatic agent concentration found in the test system; and

(iv) Evidence of the effective capacity or duration of effectiveness of the bacteriostatic agent in controlling the contaminants responsible for the identified problem occurring under simulated in-use conditions.

(2) Suggested performance standard. The effective capacity or duration of effectiveness of the bacteriostatic agent incorporated in a potable water treatment unit should be established by meaningful results that can be associated with actual in-use conditions. The data should demonstrate that microbial contaminants in municipally-treated water cause a recognized aesthetic problem (e.g. undesirable tastes or odors) in the control units without a bacteriostatic agent, and that such problems are prevented or delayed in the test units with the bacteriostatic agent.

§ 91-57 Antimicrobial agents sold only for formulation use.

(a) Type of data. The manufacturer (or registrant) of a technical chemical intended for this type of use should submit presumptive evidence of intrinsic value as antimicrobial agent. Examples of the types of presumptive tests acceptable are the following: minimal inhibitory concentrations derived from a tube-dilution type method, and zones of inhibition derived from a seeded agar plate type method.

(b) (Reserved).