FIFRA Minimum Risk Pesticides:

25(b) Product Efficacy Data Guidance

AAPCO FIFRA 25(b) Workgroup

Introduction

Per FIFRA Section 25(b), EPA has exempted certain products from federal registration. However, these products are subject to registration by individual states. States are not required to permit the sale of an exempted product simply because it is exempted under federal pesticide law. Each state may have different label and/or data requirements. For this reason, the Association of American Pesticide Control Officials (AAPCO) created a 25(b) Workgroup. The following data guidance was put together by the AAPCO 25(b) Workgroup to help companies comply with state requirements.

State Lead Agencies (SLA) require efficacy in accordance with EPA Condition 6: Label Statements – the label cannot include any false or misleading statements, as described in 40 CFR 156.10(a)(5), sections (i) through (viii). If a claim is not supported by data, it is therefore considered false or misleading and does not qualify for the 25(b) minimum risk exemption. Lack of supporting data could be grounds for denial of state registration.

This document is to serve as guidance to aid registrants in developing general study parameters that can support efficacy and claims. It does not guarantee that the product will be accepted in all states.

This guidance is effective 18 months from the Effective Date, any renewals for existing products within this period should not be impacted. Any existing inventory released for shipment before the Effective Date should not be impacted. Any existing products revised to make new efficacy claims or any new product initiated by registrant before the Effective Date are not required to follow this revised guidance document but is highly encouraged. Any existing product revised to make new efficacy claims or any new product initiated by registrant after the Effective Date should follow this guidance document. In areas where this guidance conflicts with state laws & regulations, state laws & regulations must be followed. For specific registration requirements or info on data collected on products not covered in this document, please contact the individual state regulatory agency responsible for pesticide registration.

This guidance is broken down into relevant chapters, dependent on targeted test organisms, corresponding general test methodology, and product claims/label information.

25(b) Product Efficacy Data Guidance

Chapters List

Chapter 1

General 25(b) Study Conduct & Data Collection Expectations

Revised August 2025

(see end of chapter for revision log)

1. General Study Requirements
    a. Data must be included that supports all pesticidal label claims.
    b. Data must be credible, reproducible, and replicated. GLP studies are not required, and in-house studies may be acceptable. Studies must be conducted in a GLP-like manner by a qualified Study Coordinator (i.e., someone who exhibits knowledge and expertise in a valid study design and conduct. A resume or CV may be required that clearly indicates the Study Coordinator has academic and/or real-world experience with designing and conducting scientific studies). Testimonials are not acceptable.
    c. Names and addresses of researchers conducting the evaluation(s) must be included.
2. Data should be generated with the product (formulation) submitted for registration.
    a. Data should include a minimum of three (3) replicates per treatment and control or comparator group (when applicable).
    b. Formulas tested: If a study contains more than one formulation or test substance, each treatment should consist of its own set of three (3) replicates and be tested at the same time as the comparative control replicates, or a justification should be provided as to why there is a different number of control replicates.
3. Data should include an untreated control variable. See *Negative / Untreated Control Replicates* definition.
4. When there are no existing protocols or standards to reference, a Study Coordinator should justify the need for a new study design and detail the justification in the test report.
5. Data should describe the full experimental design. This includes:
    a. Material and Methods.
    b. Full results, using standard scientific statistical procedures.
    c. Interpretation and conclusion of the results.
6. Claims regarding the diseases public health pests carry are not allowed (Example: “repels mosquitoes that may carry or transmit Zika” are not allowed). See EPA Minimum Risk Condition 4 for more details and examples of Health-Related Claims.
7. The duration of testing should align with label claims (Example: if a product claims to repel pests for 30 days, testing should include at least a fresh (0-day) and 30-day aged variable against a control).

Relevant Definitions for General Efficacy Studies & Data Collection:

The following definitions apply to all Chapters. See specific Chapters for more specific examples of definitions when they apply.

- *Application rate* – refers to the amount of product applied per pest or unit area or volume (e.g., oz/ft^2 or fl. oz./ft^3). It can also be expressed in seconds of spray per unit area or volume.
- *Directions for use* – refers to the section of a label that describes how the product is used.
- *Negative / Untreated control replicates* – in most studies, negative control replicates should be included, or a justification should be provided as to why control replicates are omitted or not equal in number. This set of replicates may be treated with water (or carrier/vehicle used in treatment solutions, when appropriate), or receive no treatment at all, but all other methodology should be consistent with treatment replicates. See each chapter's definition for more specific information.
- *Replicate* – refers to a single treatment or control that is repeated under the same or similar conditions. See each chapter's definition for more specific information.
- *Replication* – the number of treatment and control replicates required to provide robust data where efficacy / significant statistical analyses can be calculated. Generally, there should be at least three (3) control and three (3) treatment replicates in a study. If a study contains more than one formulation or test substance, each treatment should consist of its own set of three (3) replicates and be tested at the same time as the comparative control replicates.
- *Significant public health pest* – refers to a species which poses a risk to human health and may cause disease, harm, allergic reactions, and/or life-threatening situations. EPA has specified which species qualify as significant health pests in PR Notice 2023-01 or the most recent notice. See also EPA's webpage re: List of Pests of Significant Public Health Importance.
- *Treatment replicates* – this set of replicates receives application of pesticide product.
- *Vector* – an organism that transmits an infectious pathogen from one living organism to another.

Chapter 1 Revisions Log

Version Date	Summary of Revisions
August 18, 2025	Issuance of reformatted 25b efficacy guidance issued in January 2019. Created General 25(b) Study Conduct & Data Collection Expectations

Chapter 2
Guidance Specific to 25(b) Arthropod Testing

Revised August 2025
(see end of chapter for revision log)

This guidance is partially based on methodologies outlined in EPA's 810 Performance Test Guidelines, Group C Invertebrate Control Agent Product Performance Test Guidelines.

Arthropod Specific 25(b) Study Conduct/Data Collection and Claim Expectations:

1. For studies that do not involve human test subjects, conducting them as blind studies is recommended if applicable (example: comparison study)
2. Efficacy data should be submitted for *Anopheles*, *Aedes*, or *Culex* for any labeling claims against mosquitoes.
3. Efficacy data should be submitted for blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermancentor variabilis*), brown dog tick (*Rhipicephalus sanguineus*), or lone star tick (*Amblyomma americanum*) for any labeling claims against ticks.
4. Data must be included that supports all pesticidal label claims.
    a. Topical insect repellents with claims for ticks and mosquitoes should demonstrate ≥90% repellency efficacy because these pests are vectors of human disease-causing pathogens. The duration of repellency can be reported as Protection Time (PT) and Topical Insect Repellents with claims for ticks and mosquitoes must be reported as complete protection time (i.e., how long does the topical repellent work), or should demonstrate higher efficacy (e.g. ≥90%) because these pests are vectors of human disease-causing pathogens.
    b. Spatial repellents with claims to repel significant public health pests should demonstrate ≥75% efficacy, as defined in the test protocol for the product being registered.[1]
    c. If a label claims to kill a significant public health pest, testing should be done on that organism. Other non-public health pests may be grouped as acceptable.
    d. To make "knockdown", "quick kill", or "kills on contact" claims, data should show ≥90% knockdown within 10 seconds for wasps, bees, or fire ants or within 30 seconds for all other arthropods.
    e. Pesticides with claims to kill or repel a significant public health pest

[1] Washington state data requirements state that spatial repellents with claims to repel mosquitoes should demonstrate >75% efficacy.

should demonstrate ≥80% efficacy, unless specified differently in sections 5a-d above. [2]

f. Data for all other products, excluding those with claims for pests of public health importance, should demonstrate ≥60% efficacy. Some states may consider an alternative "soft claim" on a case-by-case basis for products demonstrating an efficacy lower than 60%.
   - A soft claim could include, but is not limited to: reduce, diminish, lower, weaken, shorten, suppress, subdue. Soft claims cannot include claims such as: repel, kill, knockdown.
   - Labeling of products should include an advisory statement when data does not meet efficacy data expectations. Examples:
   - The effectiveness of this product may not meet the level of protection required for EPA registered pesticides
   - This product has not been shown to protect people from biting insects for at least 2 hours.
   - Reduces or may reduce [name of pest].
   - Suppresses or aids in the suppression of [name of pest]

Relevant Definitions for Arthropod Efficacy Studies & Data Collection:

Refer to General Definitions which apply to all Chapters.

- *Bite* – refers to data collected in mosquito and biting fly topical repellent studies. The act of penetrating human skin by the mouthparts of an insect with ingestion of blood, typically associated with abdominal swelling or color change.
- *Confirmed event* – refers to data collected in topical repellent studies. It is one landing, probe, bite, or crossing followed by another similar event in the next subsequent exposure period. The first event is confirmed by the second. The second event is the confirming event.
- *Crossing* – refers to data collected in tick topical repellent studies. The act of passage by a tick from an area of untreated skin to an area of treated skin. A crossing may be quantified either or both by the distance the tick moves onto treated skin or by how long the tick remains on treated skin.
- *Knockdown / Moribund* – refers to a state in which a pest is rendered incapable of coordinated movement or unable to right itself following exposure to a pesticide product (e.g., on its back with only a single appendage twitching). Pests exhibiting this behavior should not be considered dead. Not

[2] Washington state data requirements state that pesticides with claims to kill or repel bed bugs or other pests of significant public health importance should demonstrate >90% efficacy

applicable to data points associated with topical repellent studies.

- *Landing* – refers to data collected in mosquito and biting fly topical repellent studies. The act of a flying or jumping insect or other arthropod alighting on human skin without probing or biting.
- *Mortality / Dead* – refers to a test organism death. A dead pest is one that does not move, even when poked, probed, or provided external stimuli. Mortality observations should be reported throughout the study but no later than 96 hours (about 4 days) post-treatment exposure. The reported mortality should reflect dead arthropods only. Not applicable to data points associated with topical repellent studies.
- *Negative / Untreated control replicates* – in most studies, negative control replicates should be included, or a justification should be provided as to why control replicates are omitted or not equal in number. This set of replicates may be treated with water (or carrier/vehicle used in treatment solutions, when appropriate), or receive no treatment at all, but all other methodology should be consistent with treatment replicates. For topical repellent studies, the untreated control should be included to validate the host seeking activity of the test system (arthropod).
- *Probe* – refers to data collected in mosquito and biting fly topical repellent studies. The act of penetrating human skin by the mouthparts of an insect without ingestion of blood.
- *Protection Time (PT)* - refers to data collected in topical repellent studies. PT refers to the time from application of a repellent until efficacy failure as it is defined in each study. For example, the time from application until the first efficacy failure event (land or crossing) confirmed by a second similar event in the next exposure period, or until the repellent effect drops below 90%.
- *Questing* – refers to data collected in tick topical repellent studies. The behavior of ticks actively seeking a host.
- *Replicate* – refers to a single treatment or control that is repeated under the same or similar conditions. Examples of a replicate include but are not limited to: one container of a defined number of test insects for direct treatment evaluations, an arm of a volunteer test subject for topical repellents study, one defined area of treatment for a spatial repellent evaluation.
- *Spatial repellency* – refers to data collected in a spatial repellent study. Defined as the reduction in insect populations in a defined area compared to untreated control replicates of the same defined area or a reduction in the number of lands or probes occurring in the treatment area compared to the number of lands or probes in the untreated control replicates.
- *Unconfirmed event* – refers to data collected in topical repellent studies. It is a landing, probe, bite, or crossing not followed by another similar event in the next subsequent exposure period.

Chapter 2 Revisions Log

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Chapter 3

Guidance Specific to 25(b) Antimicrobials & Surface Fungicide Testing

Revised August 2025

To help devise study designs, registrants may consult efficacy definitions, test methodology, test strains, and other guidance found in EPA's 810 Performance Test Guidelines, Group B Antimicrobial Efficacy Test Guidelines, EPA Pesticide Assessment Guidelines – Subdivision G: Product Performance, or other EPA protocols or guidance found on the EPA website. Various standard setting organizations may also provide test methodology to support claims including ASTM, AOAC, ISO, etc.

810.2000 Section (C) (2) (ii)
Testing. A crosswalk table has been provided for non-public-health claims and the OCSPP 810 Test Guideline Series (Crosswalk Table for Non-Public Health Guidelines). In certain instances, the methods used to support public health related label claims may also be used to support non-public health label claims. This crosswalk is intended to assist interested parties in determining which 810 guidelines may be appropriate for generating data to support non-public health claims. In addition, other testing approaches also may be acceptable to support non-public health label claims."

Antimicrobial Specific 25(b) Study Conduct/Data Collection and Claim Expectations:

1. If a label claims to kill a microbial pest (e.g., bacteria, fungi, algae), testing should be done on a representative strain for that type of pest or species.
2. Data for antimicrobial products should demonstrate ≥60% efficacy.
3. EPA 25(b) Antimicrobial Products are not allowed to make public health claims (See Condition 4).

Relevant Definitions for Antimicrobial Efficacy Studies & Data Collection: See 40 CFR 158.2203, EPA 810.1000, 810.2000, EPA Pesticide Assessment Guidelines – Subdivision G: Product Performance.

- *Bacteriostat* – a substance, or mixture of substances, that inhibits the growth of bacteria in the inanimate environment.
- *Disinfectant* – a substance, or mixture of substances that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate
- *Fungicide* – a substance, or mixture of substances, that destroys fungi (including yeasts) and fungal spores pathogenic to humans or other animals in the

inanimate environment.

- *Fungistat* – a substance, or mixture of substances, that inhibits the growth of fungi in the inanimate environment.
- *Non-Public Health Claim* – An antimicrobial pesticide is considered to make a nonpublic health claim if the pesticide product bears a claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans. Examples of nonpublic health claims include, but are not limited to: Algaecides, slimicides, preservatives and products for which a pesticidal claim with respect to odor sources is made.
- *Public Health Claim* – An antimicrobial pesticide is considered to make a public health claim if the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment. A product makes a public health claim if one or more of the following apply:
    - (1) A claim is made for control of specific microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include, but are not limited to: Mycobacterium tuberculosis, Pseudomonas aeruginosa, Escherichia coli (E. coli), human immunodeficiency virus (HIV), Streptococcus, and Staphylococcus aureus. Claims for control of microorganisms infectious or pathogenic only to animals (such as canine distemper virus or hog cholera virus) are not considered public health claims.
    - (2) A claim is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.
    - (3) A claim is made for the pesticide product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly state that it is intended for use only against nonpublic health fungi.
    - (4) A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.
    - (5) A non-specific claim is made that the pesticide product will beneficially impact or affect public health at the site of use or in the environment in which it is applied, and:
        - (i) The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or
        - (ii) The pesticide product is similar in composition to a registered pesticide product that makes antimicrobial public

health claims.

- *Sanitizer* – a substance, or mixture of substances, that reduces the bacterial population in the inanimate environment by significant numbers, (e.g., 3 log10 reduction or more), but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances may be used on food contact surfaces and are termed sanitizing rinses.
- *Sterilant* – a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.
- *Sporicide* – a substance, or mixture of substances, that irreversibly inactivates bacterial spores in the inanimate environment.
- *Viricide* – a substance, or mixture of substances, that destroys or irreversibly inactivates viruses in the inanimate environment.

Chapter 3 Revisions Log

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