FIFRA Minimum Risk Pesticides – 25(b) Product Efficacy Data Guidance

Per FIFRA Section 25(b), EPA has exempted certain products from federal regulation. 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. This list is for guidance purposes and does not guarantee that your product will be accepted in all states.

25(b) Pesticide Product Efficacy Data Expectations:

1. Data must be included that supports all pesticidal label claims.
    a. Topical Insect Repellents with claims for ticks and mosquitoes should demonstrate higher efficacy (e.g. ≥90%) because these pests are vectors* of human disease causing pathogens. Spatial repellents with claims to repel mosquitoes should demonstrate ≥75% efficacy.
    b. If a label claims to kill a pest of significant public health importance** , testing should be done on that organism. Other pests may be grouped as acceptable.
    c. 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 insects or spiders.
    d. Pesticides with claims to kill or repel any pest of significant public health importance, excluding microorganisms and those already mentioned above, should demonstrate ≥80% efficacy.
    e. 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%.
2. Data must be credible, independently collected, reproducible, and replicated. GLP studies are not required.
    a. Testimonials are not acceptable.
    b. Journal articles may be acceptable if, in the state's judgement, the design and conduct of the study provide results that are scientifically reliable. Note: Journal articles are not acceptable for Indiana and New Mexico
    c. In-house studies may be acceptable if the study is conducted in a GLP-like manner by a qualified study director.

*Vector is an organism that transmits a disease or parasite from one animal or plant to another.

**EPA identifies the following pests as pest of significant public health importance: cockroaches; body, head, and crab lice; mosquitoes; ticks; bed bugs; various rats and mice; various microorganisms, including bacteria, viruses, and protozoans; reptiles and birds; various mammals. For more information visit https://www.epa.gov/insect-repellents/list-pests-significant-public-health-importance.

***A soft claim could include, but is not limited to: reduce, diminish, lower, weaken, shorten, suppress, subdue. Soft claims cannot include claims like: repel, kill, knockdown.

i. A qualified study director is someone who exhibits knowledge and expertise in a scientifically valid study design and conduct. To be a qualified study director, a resume or CV may be required that clearly indicates the study director has academic and/or real-world experience with designing and conducting scientific studies.

d. Data should include a minimum of three (3) replicates per test.
e. Studies that involve humans, such as repellency testing, should be double-blind studies. Studies that do not involve humans, such as direct kill testing, should be blind studies.
f. Names and addresses of researchers conducting the evaluation(s) must be included.
g. Efficacy data should be submitted for *Anopheles*, *Aedes*, or *Culex* for any labeling claims against mosquitoes.
h. Data should address Complete Protection Time (CPT) for mosquito repellents.
i. 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.

3. 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.
4. Data should be generated with the product (formulation) submitted for registration.
5. Data should include an untreated control.
6. 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 mosquitoes for at least 2 hours.
    - Reduces or May reduce (name of pest).
    - Suppresses or Aids in the suppression of (name of pest).

This list is to serve as guidance only. This document is a living document that may be updated at any time. For specific registration requirements, please contact the individual state regulatory agency responsible for pesticide registration.