

FIFRA Minimum Risk Pesticides – 25(b) Q&A Document

As a draft – this document will also be reviewed by SFIREG and the AAPCO board.

This document is in response to questions from Industry to the 25(b) State Workgroup per the Data Efficacy guidance (published March 2019). The data guidance is to assist companies when submitting product applications to states. However, it is the company’s responsibility to have scientifically sound data on all claims, even if the data is not requested by states.

Regulation and Enforcement of Minimum Risk Pesticides

The State Lead Agencies are requiring efficacy in accordance to EPA Condition 6: Label Statements – The label cannot include any false or misleading statements, as described in 40 CFR 156.10(a)(5)(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.

For non-compliant products, a state may take enforcement action:

- Through their state regulations
- By referring the product to EPA
- By referring product claims that have determined to be misleading to the Federal Trade Commission for possible additional enforcement action.

Background

Consumer Specialty Products Association: In 2006, the Consumer Specialty Products Association (CSPA) petitioned EPA to modify the regulations for minimum risk pesticides. This petition explained that such pesticides may be sold without there having been tested for efficacy against public health pests or for safety. CSPA voiced their concern that the minimum risk pesticide exemption endangers public health. “Specifically, these untested pesticides often misleadingly and falsely claim to control public health pests with the result that consumers mistakenly and detrimentally rely upon these pesticides to protect their health.”ⁱ

Federal Trade Commission: Mosquitoes can carry serious diseases, such as Zika virus. In 2016, the World Health Organization declared the Zika virus an international public health emergency. The Centers for Disease Control and Prevention (CDC) does not know the effectiveness of non-EPA registered insect repellents, which includes minimum risk pesticides. CDC recommends using an EPA-registered insect repellent to protect oneself against diseases spread by mosquitoes.

The Federal Trade Commission (FTC) works for consumers to prevent fraudulent, deceptive, and unfair business practices. This agency has sent many warning letters to companies about anti-Zika and bed bug claims with a reminder that claims need to have sufficient supporting data (i.e. competent and scientifically sound evidence). They explained that consumer injury can follow when claims are deceptive. In 2012, FTC filed advertising charges against marketers of some 25b pesticide products who allegedly made false claims. Recently, one of the marketers of 25b pesticide products was required to pay a large penalty after violating an earlier FTC order.

Questions and Answers – Efficacy Data Guidance Document

Q1: What 25(b) products are covered with this guidance? It appears to only be for public health pest related products.

A1: All 25(b) minimum risk pesticide products are covered with this guidance. However, there is an emphasis on public health pest related products, particularly due to concerns with mosquito and tick borne diseases.

Full list of pests of significant public health importance can be found on EPA's website.ⁱⁱ

Q2: Is there a reason why the workgroup didn't go with following EPA 810 Guidelines for the 25(b) data guidance?

A2: The 25(b) data guidance was partially based on [EPA's 810 Performance Test Guidelines](#). As a workgroup, we tried to scale data requirements based on labeling claims. We acknowledged comments from industry that applying all of EPA's 810 guidelines to 25(b) pesticides may be overly restrictive.

Q3: Why are states requiring data on all claims (ie "long lasting")?

A3: Companies should be able to provide scientifically valid data for all claims. Terms such as "long lasting" are not clear and subject to interpretation by the consumer. Companies should have specific duration's of time that are supported by data.

Some states have always required data for all pesticidal claims. It is the responsibility of the company to have data to support their claims, otherwise, the product is in violation of EPA's condition 6 with false and misleading statements.

Q4: We are concerned that states lack qualified employees to review data and that this will result in inconsistent reviews.

A4: By creating this guidance, our hope is to help eliminate the possibility of arbitrary and capricious reviews. In addition, many states have entomologists, chemists, microbiologists, and weed specialists on staff or available. Also, the workgroup can collaborate and discuss concerns regarding products and information received without disclosing anything that may be proprietary.

Q5: We question why the efficacy standard for 25(b) products are equal to or more stringent than EPA guidelines for pesticides. 25(b) products are known to have efficacy but little, if any, residual. 25(b) products are inferior to traditional EPA registered pesticides, so the standards should not be the same. If 25(b) ingredients were sufficient to kill at 90%, they would not be 25(b) products, they would have made it to the EPA active ingredient list and would be federally regulated.

A5: All claims should have scientifically valid data to support them.

According to EPA, “because EPA has determined that certain "minimum risk pesticides" pose little to no risk to human health or the environment, EPA has exempted them from the requirement that they be registered under the Federal Insecticide, Fungicide, and Rodenticide Act”ⁱⁱⁱ. Therefore, the basis for inclusion as an acceptable 25(b) active ingredient was not efficacy or residual but the fact that EPA determined the ingredient presented "minimum risk".

Q6: Are any states allowing for the bridging of data? There should be a mechanism for data compensation.

A6: States interpret this question to be the bridging of data by one company for their own products.

States have not adequately assessed the quality and use of bridging data. This question will need to be addressed with each state individually. Some may allow bridging on a case-by-case basis. Some may not accept any bridging.

States are discussing the option of bridging and the possibility of establishing guidelines. This has been added to the list of requested concerns and will be addressed when the time is available.

One company cannot reference another company’s already registered product without providing the appropriate data as required by the state with the application. Industry and States agree that the ownership of data is important.

Q7: If the test is on one genus of mosquitoes, can the label claim against all mosquitoes?

A7: If the data shows the efficacy of the product meets the 90% or greater for one species (specifically referenced in the data guidance), the label can claim all mosquitoes.

The Q&A document uses OR for the species that are acceptable. Unless specified by the State, this is for all products (spatial, topical, etc...)

Q8: If data is provided for blacklegged ticks, does the label need to specify repellent against “blacklegged ticks” or is “ticks” acceptable?

A8: If the data shows the product is effective for blacklegged ticks, the label can claim the product is repellent to all ticks. For example, if the product is intended for use on cats or dogs, the appropriate tick species should be specified in the efficacy testing.

The Q&A document uses OR for the species that are acceptable. Unless specified by the State, this is for all products (spatial, topical, etc...)

Q9: Is it appropriate to test by family of a pest? When would claims not be accepted?

A9: Non-public health pest may be tested by family. All pests of public health significance must be tested to be claimed on the label.

Q10: How are states addressing products that are already in distribution and registered in their states?

A10: As states adopt the AAPCO guidelines, they may reevaluate existing registrations and make registrants aware of any needed documentation. This will depend on the individual state. Here are a few examples.

Some states will be doing a complete audit of all 25(b) products currently registered in the states to verify that all products meet these requirements. Timelines for the audits have not been determined.

If necessary, some states may address product labeling and data requirements if/when a registrant decides to submit an Application for Re-Registration of Pesticides. They may issue a Notice of Correction, which includes requirements, corrections and timelines.

Q11: Has there been any discussion on the State workgroup in regards to State laws and regulations versus using the new guidance document?

A11: Yes, the workgroup is aware that states have differing laws and regulations which may be more or less strict. The guidance is provided so states who are able to adopt it can have commonality with other states that also adopt it. In some cases, states may need to revise current laws and regulations prior to adopting in their entirety the workgroup guidance. Registrants need to understand that not all states can adopt it without changes to their state laws or regulations.

The workgroup itself is not a regulatory entity. Due to the differences in state regulations, we suggest contacting the individual state for more information. The guidance was developed based upon the most stringent state laws/policy that currently exist.

Q12: Can the workgroup provide a definition for repellency? What does it mean for difference species (like deer, rabbit, cat, dog)?

A12: According to Merriam- Webster:

Repellency = the quality or capacity of repelling

Repelling = to drive back

Another, scientific definition is “A chemical causing a responder to make movements oriented away from the stimulus source.”

Either way, that definition does not change based on the species. Some states may have a legally defined term for “repellency” and “repellent”.

Q14: Please provide clarification on what repellents are included in 1a of the Data Efficacy Guidance document.

A14: 1a refers to any product that is meant to protect an individual (person or animal) from mosquitoes or ticks (topical insect repellents – spray, lotion, wristbands, clips attached to person, etc). This includes products applied directly to the skin or worn by the individual with the purpose being to protect that individual from the pest.

Q15: What assurance can states give to industry that the study design and data will be accepted?

A15: There is a higher probability the proposed study design and data would be accepted if it supports labeling claims, reflects treatment methods, is tested on target pests and includes treatments using the same ingredients and rates shown on the product labeling. If a company has concerns regarding the acceptance of the proposed methodology for testing, they should contact the individual state with their questions.

As an example, it is recommended that your report include the following sections:

- Title page (including, at a minimum, contact information for lab and trial dates)
- Table of contents
- Test Substance Information (including, at a minimum, the different products tested, EPA Reg. Number if applicable, Active Ingredients or full formula)
- Pests tested
- Materials & Methods (including a description of the test)
- Results and Conclusion (including, at a minimum the percentage repelled/knocked-down (etc... depending on claims) based on the raw data)
- Tables showing the raw data
- Any images of the testing that would be helpful

Industry requested the 25(b) workgroup to produce a cover sheet/universal template for registrants to include with the data. The workgroup believes that if efficacy reports include the sections listed above, the additional form is not needed.

Q16: When will in-house studies be accepted? Which states accept journal articles?

A16: Many states already accept in-house studies. To get an accurate answer, a company should confirm with each state.

Some states will accept in-house studies when done by a qualified study director and utilizing appropriate methods or audited by a 3rd party to ensure the study was designed and performed in an unbiased and sound manner. The protocols and actual performance of the study should be audited at a minimum to ensure everything is on the up and up. The auditor's report should be submitted to regulators with the rest of the registration package.

Some states will accept journal articles, others will not. Registrants should confirm with each state individually.

Q17: Regarding “similar guidelines to GLP” what deviations will be deemed acceptable?

A17: Data should be competent, reproducible, and of a quality accepted by recognized experts.

States are discussing the clarifications of this requirement. This has been added to the list of requested concerns and will be addressed when the time is available.

In lieu of specific guidelines from the states, we recommend that the study include the following statement and clarifications: *“This study was conducted according to the GLP Standards with the following exceptions...”*

Q18: How will registrants be notified if the document changes?

A18: Any potential changes and the implementation timeline will be discussed either by a conference call or email (in the instance of a minor clarification or typographical error) with both the state and industry workgroups.

Q19: “Kills on contact” is listed in point 1c. What is the difference between “kills by contact” vs “kills on contact”?

A19: “Kills by contact” denotes the mode of action—the insect needs to contact the insecticide (not eat it) in order for it to work. For example, if your product is a direct spray aerosol, it kills by contact—no additional efficacy data is needed.

“Kills on contact” denotes the time it takes for the product to effectively work.

Q20: Are there any elements within a study that have caused concern with States that Industry should be aware of when creating protocols for efficacy reports?

A20: Here are some protocol concerns that States have noted.

1. A method includes “washing” of a person’s skin with soap, example unscented Dove soap prior to placing arms in a mosquito cage.
 - a. Details should be given on how much time lapsed between when the person washed with unscented soap and the test began.
2. How long should mosquitoes be held without food prior to testing
 - a. Expert review comment: *“starved for at least 24 h, to better approximate mosquitoes in the field.”*

Q21: Will States be willing to review efficacy protocols prior to the study being produced to catch any concerns ahead of time?

A21: Registrants should use a third-party expert to review efficacy protocols prior to conducting tests. It is possible some states may be able to provide a limited review of efficacy protocols prior to receiving the full application.

Q22: EPA does not require that Industry submits data for non-public health pest claims. Industry is required to have the data available upon request. Would States be willing to accept raw data for non-public health pests? (ie – not complete reports, just charts, data, etc...)

A22: Some states may accept raw data, provided it’s competent and reliable.

States are discussing this option and the possibility of establishing guidelines. This has been added to the list of requested concerns and will be addressed when the time is available.

Q23: Please provide insight as to how States are interpreting point 6 on the guidance. Point 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).”*

A23: Fraudulent claims may entice consumers to purchase and use ineffective products. When states evaluate claims about the efficacy of a pesticide, the label and labeling should not exaggerate the extent of control. Registrant may be required to drop false or unsubstantiated claims or some states may allow the option of a “softer claim” to restate an overblown efficacy claim. For example, if mosquito or bed bug populations were reduced by only 50% and the actual success was overstated on the label as “control”, then this claim might be considered by states as false and misleading.

CDC clearly instructs consumers to use Environmental Protection Agency (EPA)-registered insect repellents to protect people from mosquito bites. CDC does not know the effectiveness of non-EPA registered insect repellents, including some natural repellents. According to CDC, insect repellents have a role in disease prevention. A single bite can transmit enough infectious agents to cause disease. CDC recommends using products that have been shown to work in scientific trials. Registrants should warn consumers that their minimum risk product may not be as efficacious as EPA-registered pesticides.

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.*

The statement does not mean that states will accept products and/or efficacy that does not meet the standards outlined in the Data Efficacy Guidance.

Revision History

Date	Changes
11.29.21	Removed “DEET-free” language from Answer 5. This aligns with LC21-1208 on EPA’s Labeling Questions & Answers website

ⁱ CSPA petition: <https://www.epa.gov/minimum-risk-pesticides/personal-insect-repellents-and-minimum-risk-pesticides#exemption>

ⁱⁱ EPA Public health: <https://www.epa.gov/insect-repellents/list-pests-significant-public-health-importance>

ⁱⁱⁱ EPA: <https://www.epa.gov/minimum-risk-pesticides/minimum-risk-pesticide-definition-and-product-confirmation>