

Updates on Product Performance Rule and Guidelines

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Introduction



- The Agency registers a wide range of products intended for use against public health and structural pests, including mosquitoes, flies, cockroaches, fleas, ticks, bed bugs, ants, termites, etc.
- Product performance data demonstrate how well the pesticide product performs its intended function against pests
- Quality efficacy data can result in more accurate and effective labeling and the use of the pesticide product as intended
- Label language may be derived from efficacy data:
 - What pests are on the label?
 - Does the product kill, control, or repel the pests?
 - On what life stage is the product intended to work?
 - Where should the product be applied?
 - How long does the product work?



Summary of Presentation



- **Brief Overview of the Product Performance Rule**
- Product Performance Guidelines
- Future Work on Product Performance Guidelines

Product Performance Rule



- The final rule **was published on 4/15/22 and went into effect on 6/14/22**
- The rule codifies our current efficacy practices regarding product performance standards and which invertebrate pests to test to support labeling claims
- **The baseline performance standard is 90%**, with a few exceptions (see next slide for an example)
- The pests listed as representative species can be tested to obtain a generic claim against the applicable pest group, and species-specific claims can be made against pests for which acceptable data have been submitted and reviewed
 - E.g., if you test the representative species American and German cockroaches, you can make claims against “cockroaches,” American cockroaches,” and “German cockroaches,” assuming the efficacy data are deemed acceptable. To also make a claim against a specific pest species (e.g., Smokybrown cockroaches) you would submit additional data on that species.
- For guidance on study methodology, the 810 Series Product Performance Guidelines are still considered the go to resource
- Contacting the Agency/ submitting a protocol for review is highly recommended - especially for novel products/ pests/ claims

EPA Product Performance Rule

Labeling claim	Required test species
Dog Follicle Mite	Dog follicle mite (<i>Demodex canis</i>)
Dust Mite	Testing on one of the following species is required: American house dust mite (<i>Dermatophagoides farinae</i>) OR European house dust mite (<i>Dermatophagoides pteronyssinus</i>)
Human Itch or Scabies Mite	Human itch mite (<i>Sarcoptes scabiei</i>)

Exceptions to the baseline 90% performance standard will appear in the section of any applicable pests



Performance standards:
(1) For the dog follicle mite, the performance standard is 100 percent

(2) For the human itch or scabies mite, the performance standard is 100 percent

Product Performance Rule



- In instances where there is a conflict between one of the Harmonized Test Guidelines and the Product Performance Rule, **the Product Performance Rule supersedes the Test Guideline**
- Because the performance standards and pests to be tested are now codified, **a waiver is required** to be submitted with efficacy submissions **if the representative species or performance standards are not met but the applicant believes their data may still support the efficacy claims**
 - Waivers must be scientifically sound and justified
- Frequently Asked Questions (FAQs) website has been updated and now includes questions such as:
 - Where are the requirements located?
 - How do you submit a waiver if you don't meet the species or product performance standard requirements?

Product Performance Rule



- 158.1700 General requirements
- 158.1701 Definitions
- **158.1703 Application categories**
- 158.1704 Performance standards for data acceptability
- 158.1705 Test Guidelines
- 158.1707 Data requirement modifications
- 158.1708 Invasive species claims
- 158.1709 Invertebrate disease vector claims
- **158.1710 Structural and wood-destroying pest claims**
- 158.1712 Mites (excluding chiggers)
- 158.1714 Chiggers
- 158.1718 Ticks
- 158.1722 Scorpions
- 158.1726 Spiders
- 158.1732 Centipedes
- 158.1736 Lice
- 158.1740 Fleas
- 158.1744 Cockroaches
- 158.1748 Keds, screwworms, and bot flies
- 158.1752 Flies
- 158.1756 Mosquitoes
- 158.1768 Bed bugs
- 158.1772 Conenose bugs and kissing bugs
- 158.1776 Ants (excluding carpenter ants)
- 158.1780 Bees, wasps, yellowjackets, and hornets
- 158.1782 Carpenter ants
- 158.1784 Wood-destroying beetles
- 158.1786 Termites

Product Performance Rule



- Important wood treatment definition distinction (158.1703)
 - *Structural protection* means the prevention of termite or other wood-destroying pest activity in an entire structure as the result of an application of a pesticide product.
 - *Wood protectants and other non-structural protection* means the prevention of termite or other wood-destroying pest activity only to the treated wood (or other treated material), whereas structural protectants, however applied, claim to prevent damage to the structure.



Product Performance Rule

- Structural and wood-destroying pest claims (158.1710)
 - If an application for registration or amended registration requests a labeling claim specific to a structural or wood-destroying pest not identified in §§ 158.1782 through 158.1786, EPA may require submission of product performance data, with testing on that specific pest and subject to specific performance standards, to support those claims for effectiveness.

Product Performance Rule



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Requirements for termites and other wood destroying insects



Product Performance Rule – Pest Groups and Subgroups – Carpenter Ants

Test species:

- For products making a claim against carpenter ants, the required test species for a labeling claim appear in the following table
- The group and sub-group claims in this paragraph are for direct kill and residual surface application claims against foraging ants only (excluding colony claims)

Labeling claim

Required test species

Carpenter ants

Testing on one of the following carpenter ant species is required:

Black carpenter ant (*Camponotus pennsylvanicus*)

OR Florida carpenter ant (*Camponotus floridanus*)

OR Western carpenter ant (*Camponotus modoc*)



Product Performance Rule – Pest Groups and Subgroups – Carpenter Ants

Claim category	Performance standard
Non-Structural Protection: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection, except Baits	95% prevention of damage to wood ≥ 5 years
Structural Protection: Bait Treatment	95% prevention of damage to wood ≥ 3 years

Colony Claims:

- For colony claims, testing must be done for each species listed or each representative species, in the case of a group

Bait products or claims involving outdoor use:

- The group and sub-group claims in paragraph (b) of this section are for direct kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed or each representative species, in the case of a group.



Product Performance Rule – Pest Groups and Subgroups – Wood-Destroying Beetles

Labeling claim	Required test species
True powderpost beetles	Testing on one species from the Lyctinae subfamily is required
Wood-destroying or wood-boring beetles	Testing on three species is required: Anobiid beetle (<i>Anobiidae</i> sp.) AND Bostrichid beetle (<i>Bostrichidae</i> sp.) AND Old house borer (<i>Hylotrupes bajulus</i>)



Product Performance Rule – Pest Groups and Subgroups – Wood-Destroying Beetles

Claim category	Performance standard
Non-Structural Protection: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection, except Baits	95% prevention of damage to wood ≥ 5 years
Structural Protection: Bait Treatment	95% prevention of damage to wood ≥ 3 years



Product Performance Rule – Pest Groups and Subgroups – Termites

Labeling claim

Required test species

Pest Group Claim

Termites

Testing on species from four genera of termites is required:

Testing is required on the following *Coptotermes* termite:
Coptotermes formosanus

AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus*

AND one of the following arboreal termite species: *Nasutitermes corniger*

AND one of the following drywood termite species: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi* .



Product Performance Rule – Pest Groups and Subgroups – Termites

Pest Sub-Group Claim

Arboreal Termites

Testing of one arboreal termite species is required:

Nasutitermes corniger

Dampwood Termites

Testing of the following dampwood termite is required:

Zootermopsis sp.

Drywood Termites

Testing of one of the following drywood termites is required:

Cryptotermes brevis

OR *Cryptotermes cavifrons*

OR *Incisitermes minor*

OR *Incisitermes snyderi*

Subterranean Termites, including Formosan
Subterranean Termites

Testing in two genera of termites is required:

Testing on the following *Coptotermes* species is required: *Coptotermes formosanus*

AND one of the following *Reticulitermes* species: *Reticulitermes flavipes*
OR *Reticulitermes hesperus* OR *Reticulitermes virginicus*



Product Performance Rule – Pest Groups and Subgroups – Termites

- The Product Performance Rule specifies that, for the structural protection and wood preservative claim categories, **a claim against any specific genus of subterranean termite must be supported by data on that individual genus and all the required test genera for a subterranean termite claim must be tested and submitted**



Product Performance Rule – Pest Groups and Subgroups – Termites

Claim category	Performance standard
Non-Structural Protection: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection, except Baits	95% prevention of damage to wood ≥ 5 years
Structural Protection: Bait Treatment	95% prevention of damage to wood ≥ 3 years

Summary of Presentation



- Brief Overview of the Product Performance Rule
- **Product Performance Guidelines**
- Future Work on Product Performance Guidelines



Product Performance Guidelines

- 810 series guidelines provide guidance on testing methods for product performance studies
 - 810.3000: General Considerations for Efficacy of Invertebrate Control Agents (1998)
 - **810.3100: Treatments for Imported Fire Ants (2021)**
 - 810.3200: Livestock, Poultry, Fur- and Wool-Bearing Animal Treatment (1998)
 - 810.3300: The Efficacy of Topically Applied Pet Products Against Certain Invertebrate Pests (2021)
 - 810.3400: Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments (1998)
 - **810.3500: Premises Treatments (2019)**
 - 810.3600: Structural Treatments (1998)
 - 810.3700: Insect Repellents to be Applied to Human Skin (2010)
 - 810.3800: Methods for Efficacy Testing of Termite Baits (2004)
 - 810.3900: Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products (2017)

**Underlined guidelines have been created/revised under PRIA 4*



810.3500: Premises Treatments (2019)

- What is covered:
 - Intended to be used for testing efficacy against public health pests found on premises (e.g., mosquitoes, ticks, fleas, cockroaches, dust mites, spiders, scorpions, centipedes, flies, wasps, ants, etc.)
 - Detailed guidance on the development of protocols and the reporting of completed premises treatment studies to the Agency
 - Specific guidance for laboratory studies (direct application to pests, residual application to surfaces, ovicides, indoor foggers/space sprays, fumigants, insect growth regulators, cockroach baits, fly baits, ant baits, and flushing products)



810.3500: Premises Treatments (2019)

- What is covered (continued):
 - Specific guidance for field studies (outdoor foggers, outdoor pesticide misting systems, direct treatment and bait products for nest/hive/colony of flying stinging Hymenoptera)
 - Each specific guidance section includes recommendations on experimental units, replication, application method, exposure to treatments, data collection and endpoints, and data analysis and reporting

810.3500: Premises Treatments (2019)



- What is not covered:

- Studies for testing bed bug products (this is covered by 810.3900 Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products)
- Studies for testing wide-area mosquito/biting fly control products (e.g., aerial ULV application by mosquito control districts)

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810.3500: Premises Treatments (2019)



- What is not covered (continued):
 - Studies for testing structural protection from wood-destroying pests (e.g., soil-applied and termiticide baits intended to prevent damage to a structure)
 - Studies for testing tree-applied products for invasive borers

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Gary Airport, Harvard University, bug 5380032



Photo courtesy of USDA ARS



James Smith, USDA APHIS PPC 1460031



Product Performance Guidelines

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**Underlined guidelines have been created/revised under PRIA 4*

810.3100: Treatments for Imported Fire Ants (2021)



- What is covered in revised 810.3100:
 - Detailed guidance on the development of protocols for red imported fire ant efficacy studies for area-applied and bait products
 - Detailed guidance on the reporting of completed red imported fire ant efficacy studies for area-applied and bait products to the Agency

810.3100: Treatments for Imported Fire Ants (2021)

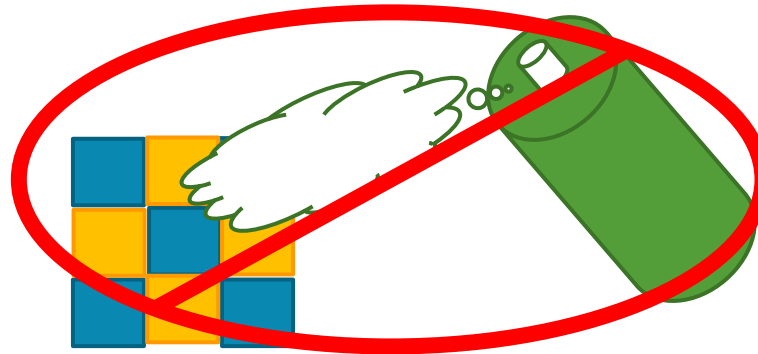


- What is covered in revised 810.3100 (continued):
 - Experimental designs for field studies testing area-applied and mound-applied pesticide products
 - Includes guidance on site selection, experimental units, replication, application method, exposure to treatments, data collection and endpoints, and data analysis and reporting
 - Experimental designs for laboratory studies testing bait, products other than baits, and insect growth regulator products
 - Includes guidance on experimental units, replication, application method, exposure to treatments, data collection and endpoints, and data analysis and reporting

810.3100: Treatments for Imported Fire Ants (2021)



- What is not covered in revised 810.3100:
 - Studies for testing direct spray products for red imported fire ants (covered in the revised Premises Guideline)
 - Studies for testing residual spray products for red imported fire ants (covered in the revised Premises Guideline)
 - Studies for testing of household-style baits for red imported fire ants (e.g., small bait stations where killing action on workers, not colony level effects, is expected) (covered in the revised Premises Guideline)



Summary of Presentation



- Brief Overview of the Product Performance Rule
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Future Work on Product Performance Guidelines

- Mosquitoes and tick guidelines
 - Updating guidelines related to wide area mosquito control products (810.3400) and skin applied repellents (810.3700)
 - Creating specific guidance for spatial repellents and impregnated clothing
 - Considering emerging technologies such as Attractive Toxic Sugar Baits (ATSBs), mosquito-disseminated products, and Genetically Modified mosquitoes
- **Termite guidelines**
 - **Updating guidelines related to structural termiticides (810.3600) and termite baits (810.3800)**
- Work on these guidelines is underway
 - Generally, efforts to create or revise guidelines can take at least 4 to 5 years
 - Resource availability also impacts guideline revision efforts



Future Work on Product Performance Guidelines

- Current termiticide guidance:
 - 810.3600 (1998)
 - Structural protection, wood preservatives
 - General considerations – site selection, number of trials, residual considerations, evaluation and reporting procedures, suggested performance standards
 - 810.3800 (2004)
 - Termite baits
 - A little more detailed regarding general considerations such as termite species, test designs, field site establishment, termite monitoring, data collection and reporting, etc.



Future Work on Product Performance Guidelines

- Issues frequently encountered with submitted termiticide data packages:
 - Raw data are not included
 - Methods description lacking adequate details
 - Data not submitted for all representative species
 - Species identification determination is not performed
 - Length of the study duration too short to support the claim(s)



Future Work on Product Performance Guidelines

- Strategy for revisions to the termite guidelines:
 - Include guidance on experimental units, replication, application methods, exposure to treatments, data collection and endpoints, and data analyses and reporting
 - Incorporate guidance to address deficiencies commonly observed in submitted data
 - Include clear expectations of what information a submitted study should contain
 - Consider the types of efficacy-related claims companies propose on their labels
 - Only recommend the collection of data that would be needed to make a determination of the efficacy of a product
 - Detailed guidance on the development of protocols
- The Rule provides requirements for duration of tests, required species and efficacy standards



Thank you!

Guideline link:

<https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines>

FAQ link:

<https://www.epa.gov/pesticide-registration/efficacy-testing-pesticides-targeting-certain-invertebrate-pests>

Final Rule is effective on June 14, 2022:

(Docket #s: EPA-HQ-OPP-2020-0124FRL-5331-05-OCSP)

<https://www.federalregister.gov/documents/2022/04/15/2022-07963/pesticide-product-performance-data-requirements-for-products-claiming-efficacy-against-certain>

Pesticide product efficacy testing questions can be sent to:

OPP_RD_INVERT_EFFICACY@epa.gov