

**FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
SCIENTIFIC ADVISORY PANEL
OPEN MEETING**

May 8-10, 2018

FIFRA SAP Website <https://www.epa.gov/sap>

Docket <https://www.regulations.gov>

Docket No. EPA-HQ-OPP-2017-0693

**U.S. Environmental Protection Agency Conference Center
Lobby Level One Potomac Yard (South Bldg.) 2777 S. Crystal Drive
Arlington, VA 22202**

**FIFRA SAP REVIEW METHODS FOR EFFICACY TESTING OF PESTICIDES USED
FOR PREMISE TREATMENTS FOR INVERTEBRATE PESTS AND TREATMENT
FOR FIRE ANTS**

TUESDAY, MAY 8, 2018

Please note that all times are approximate (see note at end of agenda).

- 9:00 AM Meeting Opening and Administrative Procedures** – Marquee D. King, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA
- 9:10 AM Introduction of Panel Members** – James McManaman, Ph.D., Chair of the FIFRA SAP
- 9:15 AM Welcome and Opening Remarks** – Daniel Rosenblatt, Deputy Director, Registration Division, Office of Pesticide Programs, EPA
- 9:20 AM Product Performance Data Requirements and the Importance of Efficacy Testing Guidance** – Daniel Rosenblatt, Deputy Director, Registration Division, Office of Pesticide Programs, EPA
- 9:30 AM Background and Introduction to Proposed Methods for Efficacy Testing of Premises and Fire Ant Treatments** – Jennifer Saunders, Ph.D., Registration Division, Office of Pesticide Programs, EPA
- 9:45 AM Draft Product Performance Test Guidelines 810.3500 Premise Treatments** – Jennifer Saunders, Ph.D., and Jacquelyn Herrick, M.S., Registration Division, Office of Pesticide Programs, EPA
- 11:00 AM Break**

11:15 AM **Draft Product Performance Test Guidelines 810.3100 Treatments for Red Imported Fire Ants** – Dee Colby, Ph.D., and Matthew Aubuchon, Ph.D.,
Registration Division, Office of Pesticide Programs, EPA

12:15 PM **Lunch**

1:30 PM **Public Comments** – Clark "Chuck" Klein, Ph.D., Global Development Manager
BASF, Urban Pest Control, Research Triangle Park, NC

Steven Bennett, Ph.D., Vice President of Scientific Affairs, Household &
Commercial Products Association, Floor Care Division Staff Executive Pest
Management Products Division Staff Co-Executive, Washington, DC

1:45 PM **Break**

2:00 PM **Panel Deliberations – Charge questions**

Premises treatment methods

1) The draft guidelines describe test methods for evaluating the efficacy of a variety of pesticides to treat premises. Please discuss:

a. Whether, given the objectives and the types of products being evaluated, the test methods are appropriate to evaluate the efficacy of premises products and to support pesticide labeling claims related to kill, knockdown, residual control, and/or flushing.

b. Whether there are additional or alternative test methods beyond those discussed in the draft guidelines for testing the efficacy of premises pesticide products.

2) In Section (d)(a)(iii), a metered bench top sprayer is given as an example of a spray device that can be used to ensure consistent application volume and even distribution of spray particles. It is also stated that when utilizing such application devices, one should ensure the deposition of the product mimics the proposed product's intended method of application (e.g. formulation type should not change between an aerosol and a liquid). Please discuss:

a. Whether a metered bench top sprayer could provide an application that would be similar to a typical liquid spray in the field. Would the bench top sprayer also provide an application that would be similar to a typical aerosol spray? Please discuss the potential of bridging efficacy data between aerosol and liquid sprays.

3) Sections (i), (j), (k), (l), (o), (p), and (q) indicate that pests should be moved to untreated containers as soon as practical but no longer than 4 hours after onset of exposure to pesticide application for crawling pests and 1 hour after onset of exposure to pesticide application for flying pests. Please discuss: a. Whether these time constraints are reasonable for most public health premises pests to predict efficacy under actual use, and why or why not. If not, what standards are recommended? Should there be differences for specific pests or residual surface types? If so, please recommend time constraints for specific pests or residual surface types.

4) Sections (j) and (k) describe studies to test the residual efficacy of premises pesticide products and include specific substrates for testing outdoor versus indoor products; sections (k), (r) and (t) propose that indoor aging of treated surfaces or baits simulating outdoor conditions may be used in lieu of actual outdoor aging. Please discuss: a. Whether there is a single surface type that could be used as a standard, representative surface for testing product residual activity in lieu of testing multiple surfaces as recommended in the draft guidelines. If so, please recommend a single surface type and discuss why it is representative of other surfaces.
b. Whether the methodology in section (k) for evaluating pesticide residues on leaves in a Petri dish is appropriate. Is a specific species of plant necessary or recommended, and if so, why?
c. Appropriate methods to simulate outdoor aging in an indoor testing environment.

4:45 PM **Recap**

5:00 PM **Adjournment**

WEDNESDAY, MAY 9, 2018

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9:00 AM Meeting Opening and Administrative Procedures – Marquee D. King, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA

9:05 AM Introduction of Panel Members – James McManaman, Ph.D., Chair of the FIFRA SAP

9:10 AM Panel Deliberations – Charge questions

5) Section (q) describes field methods for assessing efficacy of outdoor misting systems. The methods currently proposed focus on determining efficacy of direct contact with the spray only. Please discuss:

a. Whether the experimental design can be used to adequately evaluate outdoor misting systems. Given the nature of how these products are used in the field, should population reduction over time or residual efficacy in the treated area also be considered? If so, please recommend appropriate test methods.

6) Section (s) describes methods for evaluating efficacy of flushing products. Please discuss:

a. Whether the experimental design can be used to adequately evaluate flushing products. Please consider the concept of using placebo versus water-only controls and determine which allows for better determination of flushing action in the treated groups.

7) Currently only laboratory studies are proposed for assessing cockroach, fly, and ant baits (sections (r), (t), and (u)) and outdoor residual foggers (subset of section (k)). Field studies are proposed for assessing direct contact outdoor foggers (section (p)). Please discuss:

a. Whether it is necessary to also assess cockroach, fly, and ant baits and outdoor residual foggers in field studies in addition to the proposed lab studies, and why or not. If so, please recommend appropriate test methods.

b. Whether a field study as proposed is necessary to assess efficacy of direct contact outdoor fogger products, and why or why not. If not, please recommend appropriate laboratory test methods for outdoor foggers.

10:30 AM Break

10:45 AM Panel Deliberations – Charge questions

8) Sections (v) and (w) describe methods for assessing the efficacy of direct treatment of the nest/hive/colony and bait treatment of stinging, flying Hymenoptera (except ants). It is proposed that nest excavation/dissection should be conducted within 24 hours of the final at-nest assessment with

zero activity because: (1) paper nests break down quickly once the majority of the worker force has been incapacitated (i.e., killed, moribund, or knocked down), and (2) product performance claims for nest kill are typically associated with the final at-nest assessment time point (e.g., kills the nest by 7 days), since there will have been zero foraging activity for two consecutive days and it is generally assumed that the colony is dead/dying or vacated. Please discuss:

- a. Whether a 24-hour window is an acceptable length of time to allow for nest excavations and in-field dissections, and why or why not.
- b. Whether colony mortality should be defined as 100% mortality of the colony members, and why or why not. If not, what is an acceptable definition or threshold to define mortality of a colony?

9) Section (x) describes methods to determine the resistance ratio of a population. EPA's current bed bug guideline (OPPTS 810.3900) specifies a resistance ratio equal to or greater than 100 when testing against resistant strains is performed. Please discuss:

- a. Whether the resistance ratio of 100 should also apply to the pests covered in the premises guideline, and why or why not. If not, what might be an appropriate resistance ratio and why? Please comment specifically on an appropriate resistance ratio for flies, cockroaches, and mosquitoes.
- b. Whether the recommended methods are appropriate for flying and crawling species, and why or why not. If not, please recommend other methods that may be more appropriate.

10) Please provide comments on the overall clarity, accuracy, and completeness of the draft premises guidelines. Please provide any additional comments that highlight areas of the draft guidelines that may need to be clarified and note any critical topics that are missing. Please include references to published literature that could help improve the completeness and clarity of the draft guidelines.

11:40 AM Lunch

12:40 PM Panel Deliberations – Charge questions

11) Historically, the Agency has often received basic laboratory studies which utilize 5 replicates of 10 individuals. Based on the stats document provided, that replication provides power of 0.8 with 15% or 20% precision. However, with a precision of 10%, the same replication only provides a power of 0.6. This level of replication is the default recommendation in the draft premises guideline, though other levels of replication may be acceptable if submission of information from a power analysis or other justifications are provided. The Agency is specifically considering available methods to increase the statistical power of each test. Please discuss and provide comment on:

- a. The statistical methods and simulations EPA has developed to estimate the power of the proposed design, and specifically to achieve an adequate estimate of precision around the estimated mortality rate in the treated group.
- b. Using the assumptions described in the Sample Size document, options with 10% precision and power of 0.8 are 5 replicates of 15 individuals, 7 replicates of 10 individuals per replicate, or 35 replicates with 1 individual per replicate. Please comment on this conclusion and provide alternative approaches, if appropriate. Please also comment on the use of power of 0.8 and precision of 10% as generally acceptable standards. Do the panel's recommendations vary based on species and/or test? Please specify.

Fire ant methods

(1) The draft guidelines describe test methods for evaluating the efficacy of a variety of pesticides to control fire ants. Please discuss:

- a. Whether, given the objectives and the types of products being evaluated, the test methods are appropriate to evaluate the efficacy of fire ant products and to support pesticide labeling claims related to kill, colony elimination and residual control.
- b. Whether there are additional or alternative test methods beyond those discussed in the draft guidelines for testing the efficacy of fire ant pesticide products.

(2) Fire ant product field tests are described in sections (i) and (j). Please discuss: a. Whether data should be collected from locations identified with uniquely monogyne and uniquely polygyne populations, and why or why not. If social form is not a factor in the field study design, please discuss:

- i. Whether field studies should be conducted at geographically disparate sites, and why or why not.
- ii. If there is a biological reason (i.e. not a statistical reason) that more than two sites should be added to the design.

b. Section (i) describes area-applied product field tests for fire ants. Please discuss:

- i. Whether a 60-day duration is an acceptable minimum time frame to run an area-applied product study for fire ant control, and why or why not.
- ii. What the minimum number of active fire ant mounds that should be included in each plot is if the plot size is determined by the investigator. For example, if an investigator decided to set up a study in an urban area where plot sizes may be 0.1 acre, what is the minimum number of mounds that should be included in a plot? Please provide a justification for the recommended number.
- iii. Whether, when sampling foragers using vials containing a food lure, the placement of the farthest vial from the center at 90% of the radius of the plot is an acceptable distance. Would a smaller sampling radius be acceptable, and why or why not?

c. Section (j) describes mound-applied product field tests for fire ants. Please discuss: i. Whether a 30-day duration is an acceptable minimum time frame to run a mound-applied product study for fire ant control, and why or why not.

d. Sections (i) and (j) describe IGR product field tests for fire ants. Please discuss: i. Whether it is unreasonable to think that all mounds should have brood at the beginning of an IGR study; that is, do they all have to have brood or would it be acceptable if at least 90% of the active mounds had brood? Please provide a justification for the recommendations.

ii. Whether, when considering duration of an IGR product field study, if a minimum 60-day duration is an acceptable time frame to see an IGR-effect, and why or why not.

2:10 PM Break

2:25 PM Panel Deliberations – Charge questions

(3) Fire ant product lab tests are described in sections (k), (l), and (m). Please discuss:

- a. Whether the arena size used to establish test colonies should be standardized, and if so, what the size should be and why.
 - b. Whether there should be a standardized length of Tygon tubing between the nest arenas and foraging arenas, and if so, what the length should be and why.
 - c. Whether an acclimation period of 24 hours is enough time for smaller sized test colonies (e.g. 100 workers) and 72 hours is enough time for larger test colonies (e.g. 10,000 workers), and why or why not.
 - d. Section (m) describes IGR product lab tests for fire ants. Please discuss:
 - i. Whether, when considering duration of an IGR product lab study, a minimum 30-day duration is an acceptable time frame to see an IGR effect, and why or why not. Should one expect to see absence of brood, deformities of brood, dead brood, and/or changes in caste structure within 30 days?
 - e. Section (k) describes bait product lab tests for fire ants. Please discuss:
 - i. Whether 100 workers per replicate is enough individuals to initially support brood and queen(s) in a 2-week lab test, and why or why not.
 - f. Section (l) describes barrier product lab tests for fire ants. Please discuss:
 - i. Whether 100 workers per replicate is enough individuals for a 2-week lab test, and why or why not.
- (4) Please provide comments on the overall clarity, accuracy, and completeness of the draft fire ant guidelines. Please provide any additional comments that highlight areas of the draft guidelines that may need to be clarified and note any critical topics that are missing. Please include references to published literature that could help improve the completeness and clarity of the draft guidelines.

4:45 PM Recap

5:00 PM Adjournment

THURSDAY, MAY 10, 2018

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- 11:00 AM Panel Deliberations**
- 12:30 PM Adjournment**

As noted above, please be advised that agenda times are approximate. For further information, please contact the Designated Federal Official for information regarding this meeting, Dr. Marquee D. King, via telephone: (202) 564-3626 or email:king.marquee@epa.gov.