AGENDA
FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING
March 19 - 21, 2013

FIFRA SAP WEB SITE http://www.epa.gov/scipoly/sap/
OPP Docket Telephone: (703) 305-5805
Docket Number: EPA-HQ-OPP-2012-0574

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

Draft Product Performance Data Needs Assessment for Products Claiming Efficacy Against Invertebrate Pests

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

Day 1
Tuesday, March 19, 2013

8:30 a.m.	**Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
8:35 a.m.	**Welcome and Introduction of Panel Members** – Daniel Schlenk, Ph.D., FIFRA SAP Chair
8:40 a.m.	**Opening Remarks** – William Jordan, Deputy Director - Office of Pesticide Programs (OPP), EPA
8:50 a.m.	**Overview of Topic -** Lois Rossi, Division Director, Registration Division (RD), OPP, EPA
9:00 a.m.	**Draft Product Performance Data Needs Assessment for Products Claiming Efficacy Against Invertebrate Pests –** Mark Suarez, M.S.; Jennifer Urbanski, Ph.D.; Clara Fuentes, Ph.D.; Kevin Sweeney, M.S. - OPP, EPA
10:15 a.m.	**Break**
10:30 a.m.	**EPA Presentation Continued**
12:30 p.m.	**Lunch**
1:30 p.m.	**Public Comments**
3:30 p.m.	**Break**

3:45 p.m. Charge to Panel

Charge 1: Pests of economic and significant public health importance for which product performance data should be submitted (Technical Support Document (TSD) Appendix 1, Tables I and II)

Product performance data should be submitted in support of all U.S. arthropod species that are: injurious; carry, transmit, or vector a pathogen; produce allergens; cause structural damage to buildings; or are invasive, exotic species, that are controlled by pesticide use and application. Please discuss:

(a) Are the lists of species of significant public health importance and wood destroying insects complete?

(b) Are additional U.S. species, or taxonomic group(s), needed?

(c) Should foreign species, or taxonomic group(s), be included? If so, which ones should be included and why? If not, why not?

4:30 p.m. Charge to Panel

Charge 2: Establish pest groupings and identify representative taxa to support such groups in lieu of the submission of data for every species of significant public health and economic importance on a label (TSD Appendices 1 & 5)

The agency is considering establishing formal pest groupings that will permit defined, generalized label claims against assemblages of pests. These groups are taxonomically and biologically based to allow representative test organisms, where appropriate, and provide for generalized label claims against the pest grouping as a whole. Please discuss:

(a) Whether grouping pests based on taxonomy and biology is appropriate and whether additional considerations are necessary?

(b) Whether the pest groups and/or sub-groups identified below and in Appendix 1 of the TSD are appropriate and adequate? If not, how should groups be developed? Please comment specifically on the proposed groups and representative test organisms proposed in Appendix 5:

1. Dust Mites (sub-group1a)
2. Chiggers (sub-group 1b)
3. Ticks (Group 2, including sub-groups 2a, b, & c)
4. Scorpions (Group 3)
5. Spiders (Group 4, including sub-group 4a)
6. Centipedes (Group 5)
7. Human Lice (sub-group 6a)
8. Fleas (Group 7)
9. Cockroaches (Group 8)
10. Bot Flies (sub-group 9a)
11. Screwworms (sub-group 9b)
12. Filth Flies (Group 10, including 10a, b, & c)
13. Mosquitoes (Group 11)
14. Biting Flies (Group 12, including sub-groups 12 a, b, c, d, e, & f)
15. Bed Bugs and other True Bugs (Group 13, including sub-groups 13a & b)
16. Stinging Bees and Wasps (Group 14)
17. Ants, except Carpenter Ants (Group 15)
18. Carpenter Ants (Group 16)
19. Wood Destroying Beetles (Group 17)
20. Termites (Group 18, including sub-groups 18a, b, c, & d)

(c) Whether additional pest groups and/or sub-groups are appropriate? If so, please provide recommendations for representative test taxa.

5:30 p.m. Meeting Adjourns

Day 2
Wednesday, March 20, 2013

8:30 a.m. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
8:35 a.m. **Introduction of Panel Members** – Daniel Schlenk, Ph.D., FIFRA Scientific Advisory Panel Chair
8:40 a.m. **Follow-up from Previous Day Discussions**
9:00 a.m. **Charge to Panel**

Charge 3: Product performance standards (TSD Unit IX)

EPA requires, reviews, and evaluates efficacy and effectiveness data on pesticide products claiming pesticidal activity against certain types of invertebrate pests as part of the registration process. The product performance data provides information necessary to support EPA's evaluation of a label claim for a pesticide product that is efficacious against an invertebrate pest. Analysis of these data may also be used to support other types of information typically provided on labels of pesticide products, such as duration of effectiveness. EPA believes that well-designed studies, as well as scientifically-based analysis criteria, are critical to ensuring label statements regarding product performance data are reliable and consistent across different products. Important to the evaluation process is not only how well the product performs, but also the minimum acceptable level of performance.

EPA intends to specify a minimum level of efficacy (performance standard) that must be met before EPA would register the product bearing a particular kind of claim. In TSD Appendix 3, EPA has also supplied a definition for performance standard: "a benchmark or reference against which the ability of the pesticide product to control or repel an invertebrate pest species is compared." The performance standards are specified in TSD Table 12 using the terms "percent knockdown," "percent mortality," "percent repellency," and/or "complete protection time" and are also defined in Appendix 3. For the most part, similar performance standards have been used by EPA for some time in evaluating pesticide products claiming to control invertebrate pests. Please discuss:

(a) Given the testing objectives and products being evaluated, are the performance standards adequate to evaluate a minimum level of efficacy of products considered for registration by EPA?

(b) Are there any other data or additional or alternative performance standards beyond those discussed in the TSD that EPA should consider for the evaluation of product performance data and related performance claims?

10:00 a.m. Break

10:15 a.m. Charge to Panel

Charge 4: Evaluation of insect repellent efficacy data

With regard to skin-applied insect repellent products, EPA evaluates submitted efficacy data on mosquitoes and ticks and analyzes these data to determine protection times that are typically provided as claims on labels of the products. As noted in Unit VII.A of the TSD for this SAP, EPA is developing a standardized graphic for skin-

applied insect repellent products that will highlight to consumers that a product works for an estimated period of time against mosquitoes and/or ticks when the product is used as directed on the label. EPA is undertaking this initiative in order to improve and clarify pesticide product labeling for consumers and promote public health protection. EPA provides recommendations for the design and execution of repellent efficacy studies in the EPA Office of Chemical Safety and Pollution Prevision (OCSPP) Harmonized Product Performance Test Guideline, OPPTS 810.3700: Insect Repellents to be Applied to Human Skin (http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm). Additionally, EPA has developed criteria that it believes are critical to analyzing submitted mosquito and tick efficacy data in such a way that consistent, reliable, informative, and health-protective estimates of Complete Protection Time (CPT) are produced. The intended criteria are as follows:

- Based in part on discussions with the Human Studies Review Board, EPA will be using the median CPT determined using survival analysis to evaluate product efficacy/repellency for both mosquito and tick repellents.
- The median CPT will be derived from the most conservative data set per pest (lowest CPT value among the tests performed for the pest) to calculate the hours of protection listed on a label. For mosquitoes, this would be the lower CPT from the typical two field study sites where testing was performed, and for ticks, this would be the lowest CPT of all the representative tick species tested.

- Standard arithmetic rounding conventions will be used to round to a whole number of hours when the calculated CPT is not a whole number.

- The minimum performance standard (using the raw median CPT, before rounding) as outlined in Unit IX (Table 12) will be two hours. If a product does not meet the minimum hours of protection EPA would not allow the graphic to be used on the label.

Given EPA's objectives to (1) ensure the reliability and consistency of claims made for skin-applied insect repellent products to keep mosquitoes and ticks away from the typical consumer for an estimated period of time and (2) to aid consumers in their decision-making by conveying to consumers that products differ in their duration of efficacy towards these vector-borne, disease-carrying insects, please discuss:

(a) Should some of the testing parameters in test guideline "OPPTS 810.3700: Insect Repellents to be Applied to Human Skin" be described with greater specificity in order to derive consistent and reliable estimates of CPT for label claims? Please provide a supporting discussion and include references to any published literature that could inform our data collection.

(b) In the pesticide program, the Harmonized Test Guidelines have been the recommended way of generating data – they are not required. However, for testing whether a product meets a performance standard, should some aspects of test guideline "OPPTS 810.3700: Insect Repellents to be Applied to Human Skin" be changed into requirements to assist EPA, based on our analysis of resultant data, to make reliable and consistent efficacy duration judgments? If so, which aspects of the test guideline should be required elements of testing conducted to demonstrate that a product meets the performance standard?

(c) Given our intended criteria, would the whole number derived from the data analysis represent a realistic method of approximating protection times for the typical consumer?

(d) Is additional or alternative scientific advice that EPA should consider to improve the analysis of efficacy data for mosquitoes and ticks?

11:15 a.m. Charge to Panel

Charge 5: Product performance testing guidelines (TSD: Section VIII)

TSD Table 3 lists the established guidelines. Guidelines 810.3000-3600 were last revised in 1998. FIFRA SAP recommendations were considered for Guidelines 810.3700 and 3800, which were published in 2010 and 2004. A draft guideline for bed bugs, 810.3900, is in the process of revision following the recommendations received from the FIFRA SAP held in March 2012. Current EPA guidelines present a variety of approaches to testing. However, the older (1998) guidelines, in particular, generally lack adequate guidance on efficacy data development, test protocols, and representative test species. TSD Tables 4 - 11 summarize the information currently contained in these guidelines. This information provides much of the context for the discussion for this SAP meeting on revising testing guidance, producing new guidelines, and standardizing testing approaches while considering data harmonization with other regulatory agencies and the World Health Organization Pesticide Evaluation Scheme (WHOPES), to the extent possible.

EPA is considering revision of guidelines 810.3000 through 3600 only. The agency also believes that new guidelines are needed for: (1) spatial repellents; (2) insecticide impregnated fabrics; (3) attractants; and (4) fumigants, because current guidelines do not address testing and evaluation of these product types. International guidance and testing methods for consideration in guideline revision/development are also presented in the TSD. Please discuss:

(a) Are the current guidelines adequate for efficacy data development, testing, and evaluation? Please describe guideline specific revisions and recommendations.

(b) Should EPA consider including the international efficacy data development guidance and test methods described in the TSD in EPA guidelines? If so, which ones? If not, why not?

(c) Are there additional or alternative testing guidelines that EPA should consider when revising current guidelines and developing new ones? Please provide published references.

12:00 p.m. Lunch

1:00 p.m. Charge to Panel

Charge 6: Test and Study Parameters (TSD Unit X)

Part of providing guidance on product performance data development is the need to define a general approach to efficacy testing and data reporting. The TSD identifies testing parameters of importance, discusses substantiation of label claims and provides detailed data reporting and evaluation guidance. Please discuss:

(a) Assuming equal application rates for the same active ingredient:

(i) Are data collected using a technical active ingredient alone sufficient to support the efficacy of an end use product?

(ii) To characterize the efficacy of a product, should dose response data on the active ingredient also be provided in addition to end use product formulation data?

(iii) Are data collected using an end use product formulation sufficient to determine the efficacy of another end use product formulation (i.e. are additional data necessary to demonstrate equivalency between end use formulations)?

(iv) Should the agency allow the use of data collected on individual active ingredients, either on an active ingredient itself or on an end use product formulation, in the evaluation of the efficacy of end use products containing multiple active ingredients?

(b) Are the minimum effective dose data needed to determine product application rates?

(c) Should a discriminating dose be determined in order to evaluate the effectiveness of an insecticide or repellent against important or indicator pest species? If so, which species and classes of insecticides should EPA consider for discriminating dose(s) determination?

(d) Is the guidance provided on protocol development, reporting study results, and the draft Data Evaluation Record (Appendix 2) template sufficient?

(e) Are the guideline testing designs and criteria presented in the TSD adequate to guide EPA's guideline development and evaluation of efficacy data?

(f) Should EPA consider additional or alternative study parameters and reporting for use in future guideline development?

2:00 p.m. Charge to Panel

Charge 7: Determining the length of exposure and evaluation times in residual contact assays with crawling insects

Length of exposure to treated surfaces in residual contact assays conducted with crawling arthropods and subsequent evaluation times have been topics frequently debated among scientists, regulators, and registrants. As EPA develops additional guidance and protocols for residual testing of insecticides against crawling insects, the criteria for determining exposure and evaluation times should be established. Please discuss the following factors and how they should be considered in developing criteria for these assays:

(a) Mode of action of the active ingredients(s)

(b) Formulation type

(c) Pest group and life stage

(d) Surface types

(e) Forced exposure test compared to a choice test.

(f) Length of exposure time

(g) Length of post-exposure evaluation period

(h) Age of surface residues

(i) Lethal Dose (LD), Lethal Concentration (LC), and Lethal Time (LT) values

3:00 p.m. Break

3:15 p.m. Charge to Panel

Charge 8: Extrapolating from other sources of efficacy data (TSD Unit XI)

Mutual acceptance of data can reduce the costs of product development and reduce redundancy in the global registration process. Product performance studies conducted in the U.S. are typically used to provide the data that support product performance claims. However, pest control and/or repellency claims may be proposed based on data from foreign trials, public domain science literature, and/or scientific rationale using a "weight of the evidence" approach derived from existing product data. As an example, laboratory colonies of U.S. anopheline mosquito species are declining. Use of foreign (i.e., non-U.S.) anopheline species in the testing impregnated materials, spatial repellents, and some space sprays has been considered: some registrants have worked with EPA before conducting studies using the foreign species in order to produce robust data sets that could not otherwise be produced in the U.S. The same is true of sand fly testing. In addition, much data conducted in foreign countries exist for these types of use patterns. Please discuss:

(a) The usefulness of foreign species data and the applicability of these data to U.S. species. Can data from foreign species be bridged to characterize efficacy against a U.S. species? For example, should data collected with Anopheles dirus, An. gambiae, or An. funestus be used to characterize the efficacy of a product against An. quadrimaculatus or An. freeborni?

(b) For what use patterns or product types might use of foreign data be most appropriate?

(c) Should efficacy data generated outside of the U.S. be used to support products that will be or are currently registered and distributed in the U.S.?

(d) Should data found in public domain science literature be used to support product specific performance claims? Could such data be used as part of a "weight of the evidence" approach to characterize product performance?

(e) Should EPA consider sources for efficacy data other than those already used and those discussed in the TSD?

4:15 p.m. Charge to Panel

Charge 9: Definitions (TSD Appendices 3 & 4)

EPA believes that definitions of terms used to describe to product performance data are needed. EPA's draft definitions are described in TSD Appendix 3. TSD Appendix 4 includes definitions used in the European Union because the agency is considering harmonizing with other regulatory agencies to the extent it is practical and appropriate. Please discuss:

(a) Are the provided definitions clear, accurate, and complete?

(b) Should EPA consider adopting any of the definitions provided by the European Union in Appendix 4?

(c) Should EPA consider additional or alternative definitions to describe product performance data?

5:00 p.m. Meeting Adjourns

Day 3
Thursday, March 21, 2013

8:30 a.m. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
8:35 a.m. **Introduction of Panel Members** – Daniel Schlenk, Ph.D., FIFRA Scientific Advisory Panel Chair
8:40 a.m. **Follow-up from Previous Day Discussions**
9:00 a.m. **Charge to Panel**

Charge 10: Please provide comments on the overall clarity, accuracy and completeness of the agency's consideration of product performance data that might be needed as discussed in the TSD and EPA guidelines

Please provide any additional comments that highlight any areas of product performance data and guideline development that may need to be clarified or improved. Please note any relevant topics that may be missing. Please include references to any published literature that could help inform EPA when developing guidance on product data and testing guidance that might be needed to evaluate the efficacy of pesticide product used to control the pests of significant public health importance, wood-destroying insects, and invasive species.

10:15 a.m. **Break**
10:30 a.m. **Charge to Panel (continued)**
12:00 p.m. **Lunch**
1:00 p.m. **Charge to Panel (continued)**
3:00 p.m. **Break**
3:15 p.m. **Charge to Panel (continued)**
5:00 p.m. **Meeting Adjourns**

Please be advised that agenda times are approximate; when the discussion for one topic is completed, discussions for the next topic will begin. For further information, please contact the Designated Federal Official for this meeting, Joseph Bailey, via telephone: (202) 564-2045; fax: (202) 564-8382; or email: bailey.joseph@epa.gov