UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 12, 2013

MEMORANDUM

SUBJECT: Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held March 19 - 20, 2013 on Draft Product Performance Data Needs Assessment for Products Claiming Efficacy Against Invertebrate Pests

TO: Steven Bradbury, Ph.D.
Director
Office of Pesticide Programs

FROM: Joseph E. Bailey, Designated Federal Official
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy

Joseph E Bailey 6/12/13

THRU: Laura Bailey, Executive Secretary
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy

Laura Bailey 6/13/13

David Dix, Ph.D., Acting Director
Office of Science Coordination and Policy

D Dix 6/18/13

Attached, please find the meeting minutes of the FIFRA Scientific Advisory Panel open meeting held in Arlington, VA on March 19 - 20, 2013. This report addresses a set of scientific issues associated with Draft Product Performance Data Needs Assessment for Products Claiming Efficacy Against Invertebrate Pests.

Enclosure

cc:

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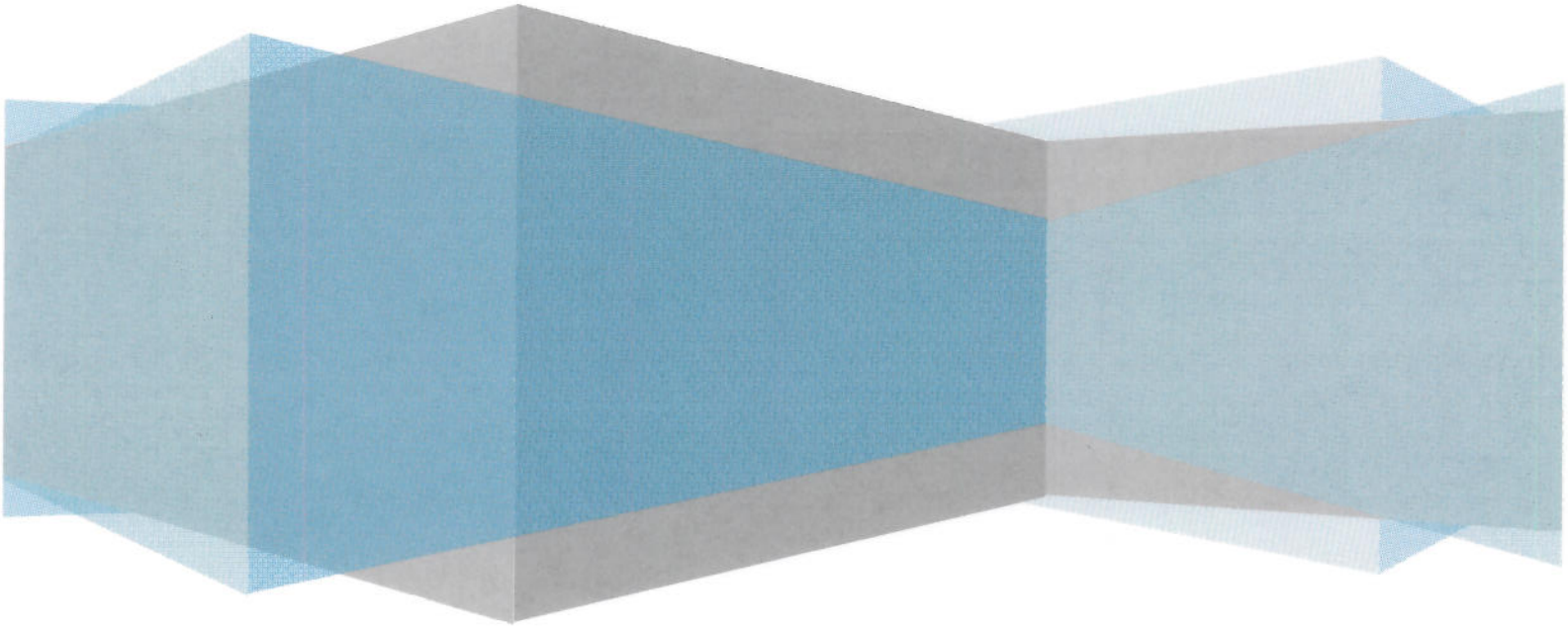
SAP Minutes No: 2013-02

A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

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

FIFRA Scientific Advisory Panel Meeting
Held at the Environmental Protection Agency
Potomac Yard Conference Center
March 19 - 20, 2013



NOTICE

These meeting minutes have been written as part of the activities of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP). The meeting minutes represent the views and recommendations of the FIFRA SAP, not the United States Environmental Protection Agency (Agency). The content of the meeting minutes does not represent information approved or disseminated by the Agency. The meeting minutes have not been reviewed for approval by the Agency and, hence, the contents of these meeting minutes do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the Federal Government, nor does mention of trade names or commercial products constitute a recommendation for use.

The FIFRA SAP is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act and established under the provisions of FIFRA as amended by the Food Quality Protection Act (FQPA) of 1996. The FIFRA SAP provides advice, information, and recommendations to the Agency Administrator on pesticides and pesticide-related issues regarding the impact of regulatory actions on health and the environment. The Panel serves as the primary scientific peer review mechanism of the Environmental Protection Agency, Office of Pesticide Programs (OPP), and is structured to provide balanced expert assessment of pesticide and pesticide-related matters facing the Agency. FQPA Science Review Board members serve the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP. Further information about FIFRA SAP reports and activities can be obtained from its website at http://www.epa.gov/scipoly/sap/ or the OPP Docket at (703) 305-5805. Interested persons are invited to contact Joseph E. Bailey, SAP Designated Federal Official, via e-mail at bailey.joseph@epa.gov.

In preparing these meeting minutes, the Panel carefully considered all information provided and presented by EPA, as well as information presented by public commenters.

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

March 19 - 20, 2013
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Held at the
Environmental Protection Agency Conference Center
Arlington, VA

Daniel Schlenk, Ph.D.
FIFRA SAP Chair
FIFRA Scientific Advisory Panel
Date: JUN 12 2013

Joseph E. Bailey
Designated Federal Official
FIFRA Scientific Advisory Panel
Date: JUN 12 2013

Federal Insecticide Fungicide and Rodenticide Act
Scientific Advisory Panel Meeting
March 19 - 20, 2013

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INTRODUCTION

The Federal Insecticide, Fungicide and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) has completed its review of the scientific issues associated with the Draft Product Performance Data Needs Assessment for Pesticide Products Claiming Efficacy Against Invertebrate Pests. Advance notice of the meeting was published in the Federal Register on December 28, 2012. The review was conducted in an open panel meeting held in Arlington, VA, on March 19 - 20, 2013. Dr. Daniel Schlenk chaired the meeting. Joseph E. Bailey served as the Designated Federal Official. Opening remarks at the meeting were provided by William Jordan, Deputy Director, Office of Pesticide Programs (OPP) and Lois Rossi, Director, Registration Division, OPP. Technical presentations were given by Mark Suarez, M.S., Jennifer Urbanski, Ph.D., Clara Fuentes, Ph.D., and Kevin Sweeney, M.S., all of OPP.

Recent developments in vector-borne diseases, such as the spread of West Nile virus, outbreaks of Dengue fever in Florida, and epidemic Rocky Mountain spotted fever on Indian Lands, together with the re-emergence of bed bugs in public housing and multifamily dwellings, have signaled the need to more carefully assess the threat of invertebrate pests to public health. At the same time, invasive wood-destroying insects such as the Emerald Ash Borer (*Agrilus planipennis*) and the Asian long-horned beetle (*Anoplophora glabripennis*) present significant economic impacts to homes and native plant species. EPA-registered insecticide products are an important part of pest management programs and consumer efforts used to accomplish pest control. EPA is considering the product performance data needed to support the registration of pesticide products claiming efficacy against invertebrate pests of significant public health or economic importance. The data being considered include a category of invertebrate pests identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.). The other two categories that are considered to be of significant economic importance are wood-destroying insects (e.g., termites) and invasive invertebrate species.

In response to these recent developments, EPA is considering the product performance data that might be needed for EPA to evaluate the efficacy of pesticide products used to control invertebrate pests. The Office of Pesticide Programs met with the FIFRA SAP to consider certain scientific issues identified during the Agency's internal discussions and deliberations. The main topics for consideration by the FIFRA SAP were the science criteria for: 1) identifying public health pests, wood-destroying insects, and invasive species for which product performance data are needed; 2) evaluating pest groupings and selection of appropriate surrogate species for efficacy testing; 3) adequacy of the performance standards being considered; 4) providing consistency in product performance studies submitted to EPA; and 5) ensuring the likelihood that EPA-registered products will perform as expected. EPA also believes that revision of these product performance data requirements will improve the transparency of its practices to the public and registrants.

PUBLIC COMMENTS

Oral Statements were presented as follows:

Ulrich Bernier, Ph.D., U.S. Department of Agriculture, Agricultural Research Service, Center for Medical, Agricultural and Veterinary Medicine
Liza Fleeson, Virginia Department of Agriculture and Consumer Services and Steve Dwinell, Florida Department of Agriculture and Consumer Services on behalf of the Association of Structural Pest Control Regulatory Officials
Janet Kinz-Early, Ph.D., on behalf of Nisus Corporation
Julie Spagnoli, Exponent, Inc., on behalf of Responsible Industry for a Sound Environment
Robert R. Steward, Ph.D., Vice President of Business Development for TSG, on behalf of Consumer Specialty Products Association
Robin G. Todd, Ph.D., BCE, on behalf of i2L Research USA, Inc.

Written Statements were provided by:

Anonymous
Joseph Bischoff, Ph.D. and Lin Schmale, on behalf of American Nursery & Landscape Association and Society of American Florists
Brian T. Forschler, Termiticide Scientific Review Panel
Jill C. Geyer, S.C. Johnson & Sons, Inc.
Gene Harrington, National Pest Management Association
Dudley Hoskins, Responsible Industry for a Sound Environment (RISE)
Derrick Lastinger, President and Steve Dwinell, Termiticide Standard Committee, on behalf of Association of Structural Pest Control Regulatory Officials
Beth L. Law, Consumer Specialty Products Association
Susan Little, Consumer Specialty Products Association, on behalf of DEET Task Force/Steering Committee/Joint Venture
Jean Public
Thomas G. Shelton, U.S. Department of Agriculture, Forest Service
Michael Watson, Ph.D., U.S. Department of Agriculture, Animal and Plant Health Protection Service, Plant Protection and Quarantine

SUMMARY OF PANEL DISCUSSION AND RECOMMENDATIONS

Charge Question 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).

(a) Are the lists of species of significant public health importance and wood-destroying insects complete? The Panel unanimously agreed that the lists in Appendix 1, Tables I and II were generally complete, but the Panel identified omissions from the list and provided suggestions for pests that may be considered for inclusion. The insects omitted were predominantly pests of veterinary importance, and it was not clear whether or not they should be included.

(b) Are additional U.S. species, or taxonomic group(s), needed? The Panel believed that additional taxa/species are needed and a number of specific taxa/species were identified for consideration along with some corrections to the list. The suggested additions are not species that are directly related to human health, but are related to human surroundings and could have the potential to affect human health.

(c) Should foreign species, or taxonomic group(s), be included? If so, which ones should be included and why? If not, why not? The majority of the Panel agreed that foreign species should be considered on a case-by-case basis when local research indicates that a particular species is likely to gain (in the near future) or has already gained a foothold in the United States (U.S.).

Charge Question 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). Please discuss:

(a) Whether grouping pests based on taxonomy and biology is appropriate and whether additional considerations are necessary? The Panel concluded that grouping of pests taxonomically was appropriate, since this tool is used in scientific research to categorize and identify taxa and their relationships. However, they also noted that just as important is pest biology, because pest location and behavior directly affects pest management methods. The current EPA technical support document (TSD) Appendix 1, Tables I and II lack detail taxonomically, as well as other considerations. The Panel suggested revisions to the tables and to the pest groupings.

(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. The Panel stated that Appendix 1, Tables I and II require additional details and they also suggested additional pest species for inclusion. As stated in the response to Charge Question 1, the Panel members wondered where the line might be drawn regarding inclusion of veterinary pests since the SAP meeting was convened to address pests of "significant public (human) health importance". During the redrafting of Appendix 1, Table I, the Panel's collective

thought progressed to retaining organisms of veterinary significance in the table. Most of the Panel members were satisfied with representative test species in Appendix 5, but with some exceptions.

(c) Whether additional pest groups and/or sub-groups are appropriate? If so, please provide recommendations for representative test taxa. The Panel suggested that pest groups for stored food and product pests and urticating caterpillars be considered for addition. Also, a group for live tree pests was suggested.

Charge Question 3: Product performance standards (TSD Unit IX).

(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? The Panel recommended that each of the groups of insects should have a separate table with performance standards. The Panel believed that the levels of 95% proposed in Table 12 were much too general to be applicable in all situations and that there should be performance standards specified per group of insects and per intended use. The Panel suggested the general standards of 95% should be reserved for cases where no other specific standards have been established.

(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? The Panel concluded that a standard performance level of 95% for all uses and all groups was not advisable and that the different performance standards in the different guidance documents were confusing. There was no complete set of guidance documents, except for some on the species level and others in regard to structures such as premises, buildings or wood. The Panel recommended one logical complete set of guidance documents that would include performance standards with field use(s) and preferably based on arthropod groups or on specific target organisms. The Panel suggested that a decision should be made in regard to standard product performance levels for each combination of product types (e.g., baits, preventive treatments, curative treatments, insect growth regulators (IGR), repellents, etc), group(s) of arthropods to be controlled, and treatment site/locations. For any combinations not covered by the list of specific standard performance levels established, the Panel suggested having one general standard performance level such as 95 - 100% kill in the lab and 90 - 95% kill in the field. In special cases, EPA should have the authority to overrule these standards if proper justification is provided by the applicants with regard to why the standards should not be applicable to a particular product.

Charge Question 4: Evaluation of insect repellent efficacy data.

(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 Complete Protection Time (CPT) for label claims? Please provide a supporting discussion and include references to any published literature that could inform our data collection. While the Panel understood during the meeting that EPA did not intend to revise Guideline 810.3700, they made a number of recommendations to improve it.

The Panel believed that the definition of "crossing" needed clarification because it could have two different measurable outcomes as it is defined now. They also recommended establishing the dose used across all repellency studies rather than allowing flexibility in determining the typical consumer dose. Outcome or measurement of repellency should be the same across studies in order to create a database of results that are comparable. Allowing flexibility in insects (orders Diptera, Siphonaptera, etc.) and in landing versus bite versus probe will result in data that cannot be compared. Sample size is critical and power analysis is the best way to ensure there is an adequate number of replicates. The Panel concluded that positive and negative controls are also essential and that sample size and controls are basic elements of good experimental design and should be employed.

(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? The Panel believed that if the goal of EPA is to create a system whereby a standard label could be applied to repellent labels, then registrant-generated data must be comparable. The guidelines currently allow registrants flexibility in most of the testing methods and in measuring outcomes. Allowing flexibility in testing methods and how outcomes are measured introduces more variability and makes it more difficult to reasonably compare field studies across different products.

(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? The Panel believed that use of whole numbers is a realistic approach to estimate CPT, but they recommended rounding down rather than up.

(d) Is [there] additional or alternative scientific advice that EPA should consider to improve the analysis of efficacy data for mosquitoes and ticks? One Panel member recommended using different CPTs on a product label for different mosquito species. Additionally, in laboratory tests, using a set number of mosquitoes per cm^3 rather than requiring a specific cage size would provide laboratories some flexibility.

Charge Question 5: Product performance testing guidelines (Technical Support Document (TSD): Section VIII).

(a) Are the current guidelines adequate for efficacy data development, testing, and evaluation? Please describe guideline specific revisions and recommendations. The Panel concluded that Guideline 810.3000 (General Considerations for Efficacy of Invertebrate Control Agents) was not very informative. They suggested the guideline include information, definitions, considerations and decisions from the EPA TSD and recommendations from this FIFRA SAP meeting to cover all products that are not covered in the specific guidelines 810.3100-3800. The Panel supported the general improvements suggested by EPA in the TSD for Guidelines 810.3100 through 3600, but they also suggested adding the following: 1) considerations on

resistance development, 2) minimum performance standards may have to be adapted and specified and 3) requirements or protocol standards for laboratory tests, simulated-use tests and field tests. In summary, the Panel concluded that the whole set of guidelines needs to be revised and updated with the addition of more information, standard procedures and performance standards and test protocols. Additionally, reorganization between the existing set of guidelines and new guidelines was suggested. The intent is to design a complete set of logical guidelines that address arthropods which impact human health, their structures and possessions, pets and domestic animals.

(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? The Panel stated that there are a number of preexisting international guidelines that might be considered by EPA to help improve or modify its own guidelines.

(c) Are there additional or alternative testing guidelines that EPA should consider when revising current guidelines and developing new ones? Please provide published references. The Panel advised EPA that when revising the older guidelines, all available data and information from international organizations, published literature, companies and stakeholder organizations (such as those that submitted comments during the March 2013 FIFRA SAP meeting) should be gathered. Also, experts in arthropod groups and/or target pests should be consulted to further improve the guidelines.

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

(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? The Panel unanimously agreed that data collected using the technical active ingredient alone was not 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? The majority of the Panel thought that in order to characterize the efficacy of an end use product formulation, dose-response data on that formulation was needed, but not dose-response data for the active ingredient. A minority opinion was that dose-response data on the active ingredient should also be provided. The Panel also noted that without dose-response data for the active ingredient, interactions (e.g., synergism versus additive effects) between the active ingredient and other components of the formulation are impossible to discern.

(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)? The Panel unanimously agreed that the efficacy of formulated products for a given active ingredient should be established in separate bioassays or field experiments because of variability among different formulations of the same active ingredient. In other words, the ingredients of a formulation can have profound effects on how it performs.

(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? The Panel unanimously agreed that having data on the efficacy of each active ingredient would be informative, but these data would not be sufficient to understand the efficacy of end use products containing multiple active ingredients. Data on the efficacy of the blended end use product is critical.

(b) Are the minimum effective dose data needed to determine product application rates? There were differences of opinion among the Panel members in response to this question. Some believed that minimum effective doses may be required of end use products and others believed that if a product was effective at a specified application rate, it was not essential for the end user to know how little can be applied to have a treatment failure.

(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? The Panel agreed that a discriminating dose was usually derived from dose-response data. A discriminating dose was suitable for differentiating insecticide susceptible and resistant populations of an arthropod species. Dose-response bioassays are the best method of evaluating the susceptibility of any given arthropod species to an insecticide and for comparing the susceptibility of different geographic populations of the same species.

(d) Is the guidance provided on protocol development, reporting study results, and the draft Data Evaluation Record (Appendix 2) template sufficient? In general, the Panel believed the guidance provided is adequate, but some mechanism for study protocol flexibility may be appropriate. Recording of field versus laboratory studies may need a different set of parameters.

(e) Are the guideline testing designs and criteria presented in the TSD adequate to guide EPA's guideline development and evaluation of efficacy data? For mosquitocides, the guidelines are adequate for laboratory testing; however, examples of additional parameters that need to be documented for field studies should be included. The Panel believed that EPA should consider convening a separate panel to address this important question.

(f) Should EPA consider additional or alternative study parameters and reporting for use in future guideline development? The Panel believed that well-controlled laboratory assays should be required for repellent testing and that field studies should be conducted to verify laboratory study results. Additional information about residual and shelf life of some end use products might be useful.

Charge Question 7: Determining the length of exposure and evaluation times in residual contact assays with crawling insects.
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): The Panel did not believe that the mode of action of the toxicant is critical to the development of the assay. The same assay involving forced contact with residues of the active ingredient that penetrate through an arthropod's cuticle could be used for crawling pests regardless of whether the active ingredient acts as an insect growth regulator or blocks the sodium channel. The assay should reflect the mode of exposure to the toxicant under operational conditions.

(b) Formulation type: The formulation type would need to be matched to the mode of exposure of the arthropod and the longevity requirement of the treatment. Assays for different types of formulations need to be developed based on the mode of exposure.

(c) Pest group and life stage: The Panel noted that different arthropod life stages are affected differently by the amount of active ingredient required to kill and they indicated that habitat and behavior of an arthropod life stage is critical to assay development.

(d) Surface types: The Panel indicated that the amount of active ingredient deposit required for intoxication on various surface types varies and also depends on the arthropod's habitat and behavior.

(e) Forced exposure test compared to a choice test: Most insecticides are ineffective in choice tests, but highly effective in forced exposure. Forced exposure will reveal the intrinsic susceptibility of an arthropod to the active ingredient. A choice test will reveal any repellent characteristics of the formulated product.

(f) Length of exposure time: As pointed out by the Panel, exposure times vary and also depend on the toxicity of the formulated product and the mode of exposure. Some toxicants gain entry into arthropods quickly, so the exposure period should be relatively short.

(g) Length of post-exposure evaluation period: Periodic readings are necessary until an end point is reached for residual surface treatments. This will depend on the length of protection required.

(h) Age of surface residues: Assays of bioactivity should be designed to incorporate measurements at time scales that reflect the length of time protection is needed.

(i) Lethal Dose (LD), Lethal Concentration (LC), and Lethal Time (LT) values: What toxicity parameter to use to characterize arthropod susceptibility depends on the nature of the assay. If arthropods consume a bait product, then the amount consumed can be measured and the toxicity of the active ingredient can be characterized in terms of the Lethal Dose. If arthropods were exposed to the end use product or an active ingredient where the amount absorbed or consumed was unknown, then the activity of the end use product or active ingredient should be described in

terms of its Lethal Concentration. If the assay involves estimation of the amount of time to an endpoint, then Lethal Time should be used as the parameter to characterize the activity of the end use product or active ingredient.

Charge Question 8: Extrapolating from other sources of efficacy data (TSD Unit XI). 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? In order to bridge foreign data, the Panel believed that some consideration of the species or species complexes involved as well as the nature of the experimental work is required. Non-native (foreign) species data can be very useful, and relevant in the case of certain groups of species. It depends on whether the non-native species are similar to the U.S. species. Life cycle, behavior, ecological adaptation, and pesticide susceptibility should be similar among native and non-native test species. Efficacy data on non-native species can be useful if the data were collected using a protocol similar to EPA's and could be strengthened with the weight of evidence of peer-reviewed publications. Such data should be considered on a case-by-case basis. The Panel recommended developing a table(s) for comparison based on differences in product formulation, use, target species, and environment in order to assess the suitability of the foreign data.

(b) For what use patterns or product types might use of foreign data be most appropriate? The Panel thought that foreign data might be appropriate for use in the following situations: 1) screening data to establish efficacy or lethal dose against cosmopolitan pests, 2) simulated field studies or applications involving artificial habitats, 3) field data with repellants applied to humans, and 4) for quarantine pests or invasive species. Caution should be exercised before accepting efficacy data from foreign sources where the conditions, environment, material applied, or species/species complexes are very different from those seen in the U.S. Further, ethical standards must be met.

(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.? The Panel believed that data generated outside of the U.S. could certainly be used to support U.S. products if it could be demonstrated that the conditions in the foreign trial(s) were equivalent to U.S. conditions and that the formulations, etc., used outside the U.S. would be similar to those proposed for U.S. use.

(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? Data available in peer-reviewed papers or credible scientific literature could be useful in supporting product specific performance claims if the efficacy protocol was similar to that used by EPA. The publication should contain the original data (not just summaries) and information on the formulation of the product (not just the active ingredient) should be clear. A justification and summary of the new application is needed.

(e) Should EPA consider sources for efficacy data other than those already used and those discussed in the TSD? The Panel believed that if the sources can be fully reviewed and verified, then they should be considered. The practical experience of a group or organization of experienced and certified pest management professionals in the field may provide additional information that could be used to support a field efficacy claim.

Charge Question 9: Definitions (TSD Appendices 3 & 4).

(a) Are the provided definitions clear, accurate, and complete? In general, the Panel believed that many of the definitions were incomplete and many were not current. They should be reviewed and revised accordingly to reflect current scientific and industry thinking. Many of the EPA definitions were not clear, but by using European Union (EU) comparable definitions when appropriate, a better quality text could be produced. Therefore, EPA should consider a review of all technical terms in the guidance documents.

(b) Should EPA consider adopting any of the definitions provided by the European Union in Appendix 4? The Panel agreed that EPA should consider adopting definitions provided by the EU in Appendix 4 of the TSD because the EU definitions were easy and clear to understand and would be useful additions. Furthermore, the Panel thought that all of them were applicable.

(c) Should EPA consider additional or alternative definitions to describe product performance data? The Panel thought EPA should consider additional or alternative definitions to describe product performance data and update them periodically as the science advances and as new health and environmental concerns are raised.

Charge Question 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. The Panel believed that EPA's TSD was fairly informative, but pointed out the importance of clarifying the scope of the document, especially with regard to whether or not livestock pests should be included. It would seem appropriate to include them, since pets were included. New guidelines for product performance could also include traps that contain semiochemicals as attractants. The EPA pest tables should be reviewed for consistency; however, in response to Charge Question 2, the Panel provided extensive revisions to Appendix 1, Tables I and II. Positive controls for repellents may neither be necessary nor should they always be required. Treatments are set by the objectives of a study. In the current protocols, there were a number of cases (Table 4) of unbalanced experimental design. This should not be encouraged. Issues such as defining replicates should be made clear for various types of protocols, as well as the issue of pseudoreplication and confounding factors (for example, pastures and treatments). The Panel commented that polygynous, polydomous colonies of arthropod species pose a considerable challenge in meeting performance standards. For these, the performance standards need to be clearly established for monogynous, monodomous forms versus polygynous, polydomous species. Regarding invasive species, the Panel stated that many pest species were actually introduced and performance standards for these species need to be developed on a case-by-case basis as they become established.

DETAILED PANEL DELIBERATIONS AND RESPONSE TO CHARGE

Charge Question 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?

Panel Response – The Panel unanimously agreed that the arthropod lists in Appendix 1, Tables I and II were generally complete, but the Panel did identify omissions from the list and have provided suggestions for pests that may be considered for inclusion. The insects omitted are predominantly pests that are of veterinary importance, and it was not clear to the Panel whether they should be included or not. This depended on the scope of the regulation. The Panel members assumed they were considering species that were injurious; carry, transmit or vector a disease causing pathogen; produce allergens; cause structural damage to buildings; or were invasive, exotic species (Section V of the TSD). Appendix 3 defined an invertebrate public health pest as: "an invertebrate species which poses a risk to man, by transmitting pathogens which cause disease, harm, allergic reactions, and life threatening situations." Appendix 3 included a definition of a public health claim as: "a claim is made to control, kill, knockdown, and/or repel specific invertebrate organisms that are directly or indirectly infectious or pathogenic or injurious to humans (or both humans and animals)." In addition to suggested additions, the Panel questioned whether some of the pests listed should be included. Appendix 1, Tables I and II, are included in these meeting minutes includes the Panel's suggested revisions.

As noted above, some of the pests listed were purely of veterinary importance and the Panel was unsure if they should be included. If the veterinary arthropods were included, then poultry pests should also be listed. These would include Northern fowl mite (*Ornithonyssus sylviarum*), red mite (*Dermanyssus gallinae*) and chicken body louse (*Menacanthus stramineus)*. If pests of purely veterinary importance were not to be included, then some species that should be considered for removal are cattle ticks (*Rhipicephalus* (*boophilus*) spp.), louse families Menoponidae and Philopteridae (poultry lice), Boopidae (marsupial and dog hosts), Gyropidae (guinea pig and rodent hosts), Trichodectidae (biting lice), sheep keds, (*Melophagus ovinus*), *Gasterophilus* (primarily parasites of horses), *Musca autumnalis* (face fly: pest of horses and cattle) and *Haematobia irritans* (horn fly: pest of cattle and horses; however, almost never bites humans). Megachilid, Halictid, Apid, Colletid,and Crabronid bees should also be considered for removal from Appendix 1, Table I.

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

Panel Response - The Panel believed that EPA should consider adding more taxa and species to Appendix 1, Tables I and II. Some species that are not directly related to human health, but are related to human surroundings, and may be considered for addition to Appendix 1, Tables I and II include the following:

- Carpet beetles (Family: Dermestidae): black carpet beetle (*Attagenus megastoma*), varied carpet beetle (*Anthrenus verbasci*), furniture carpet beetle (*A. flavipes*), common carpet beetle (*A. scrophulariae*), bird nest carpet beetle (*A. pimpinellae*), tissue paper or odd beetle (*Thylodrias contractus*). Larvae of *A. verbasci* do possess barbed hairs (hastisetae) which can cause dermatitis.

- Clothes moths (Family: Tineidae): webbing clothes moth (*Tineola bisselliella*) casemaking clothes moth (*T. pellionella*), carpet moth (*Trichophaga tapetzella*)

- Stored goods insects and mites - grain, flower, rice beetles (*Tribolium, Sitophilus, Plodia* spp.); flour mites (*Acarus* spp.)

- Tropical fire ant (*Solenopsis germinata*)

- Mange mites (e.g., psoroptic and chorioptic mange) could be included with sarcoptic mange mites.

- Parasitic mite species (particularly in the genera *Dermanyssus, Ornithonyssus*, and *Liponyssoides)* are not primarily pests of humans, but will attack humans if bird nests or flocking areas have been vacated. *Liponyssoides* mites have the potential to vector *Rickettsia akari* (Rickettsialpox) to humans, and apparently occur in the U.S. A case of bird mite infestation which occurred in Wollongong in mid-December 1996 was reported (Watson, 2003).

- There are other species of mites, such as *Pyemotes*, that will cause itching and rashes in humans.

- *Hydrotaea aenescens* and *leucostoma* are vectors of various pathogens in poultry (Szalanski et al., 2004). However, these also have some potential as biological control agents for muscoid flies.

- Under bot flies, the human bot, *Dermatobia hominis,* should be retained as this is frequently introduced by travelers. Other members that might be considered are *Hypoderma* spp. and *Oestrus ovis*. The *Gasterophilus* species listed are parasites of horses.

- The family Psychodidae also includes various species of moth flies. These are in the subfamily Psychodinae.

- *Drosophila repleta* can be produced in large numbers in animal wastes and annoy human workers.

- Litter beetles, such as *Alphitobius diaperinus*, can act as reservoirs for various food-borne pathogens.

- False blister beetles (family Oedemeridae , *Oxycopis mcdonaldi*) can cause skin blistering according to several reports (Arnett, 2000).

- Urticating (stinging) caterpillars could be included as a group. There are many species in various families. Representative families include slug caterpillars (Limacodidae), flannel moths (Megalopygidae), tussock moths (Lymantriidae), dagger moths (Noctuidae), tent caterpillars (Lasiocampidae), smokey moths (Zygaenidae), prominents and datanas (Notodontidae) and nymphalid butterflies (Nymphalidae).

- Yellowjacket wasps (*Vespula pensylvanica, Vespula maculifrons, Vespula germanica*).

- True powderpost beetles (family Lyctidae, *Lyctus* spp.) present a "high" risk potential for logs and chips and consequence of introduction is "high" (Haverty, 2003).

- Old house borer (*Hylotrupes bajulus*) or long horn beetle in the family Cerambycidae

Additional corrections to Table I include the following:

- Scabies mites should have the species name *Sarcoptes scabei* listed for human itch mite.
- The families Linognathidae and Hematopinidae are actually families of lice, not mites.
- Scientific name for house fly is *Musca domestica*, not *domesticus*.

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

Panel Response - The majority of the Panel agreed that foreign species should be considered on a case-by-case basis when research in the U.S. indicates that a particular species may likely gain (in the near future), or has already gained, a foothold in the country. Appendix 1 is fairly comprehensive in the selection of nuisance and pest arthropod species. Some foreign species of ticks, for example, could be covered by the broader taxonomic category Ixodidae or Argasidae and some fly species might be covered by Muscidae, Calliphoridae, and Sarcophagidae. Tsetse fly is not included in Appendix 1 because the likelihood of it establishing populations in the U.S. is small. On the other hand, the Old World Screwworm (*Chrysomya bezziana)* has the potential to become a problem, since the U.S. has climate zones and habitats suitable to support it.

The list for mosquitoes includes the most important genera from a worldwide perspective. Rather than generate a comprehensive list of pest mosquitoes for which certain pesticide treatments may be applied, it may be more useful to use the current list of mosquito

genera for these types of products (i.e., space sprays, larvicides) and apply a listing of foreign species in association with others (i.e., repellents, indoor residual sprays, impregnated materials). These products might be used overseas as well as in the U.S. In drafting a product label, a footnote might state that identified foreign mosquito species are not present in the U.S. Additionally, arthropods cited in Appendix 5, with the addition of *Anopheles stephensi,* might be included for consideration with personal protection products.

Regarding invasive species, the EPA response on this subject (TSD, page 11) is acceptable: " Due to sudden appearance and often rapid spread of invasive species, EPA does not presently intend to list the specific invasive species for which product performance data might be deemed necessary. Instead, the submission of product performance data to support claims for effectiveness against invasive invertebrate pest will be considered on a case-by-case basis." A new pesticide product (or addition of invasive species of concern on a preexisting product label) that may be needed in the U.S. to contain the rapid spread of an invasive species could be approved under an experimental use permit (EUP). However, it is suggested that while allowing a pesticide product to be used under an EUP on a case-by-case basis, EPA should ensure that the manufacturer (product registrant) has followed Good Laboratory Practices (GLP) and, at a minimum, has followed the North American Free Trade Agreement (NAFTA) harmonized guidance for terrestrial field dissipation studies. These studies are conducted to demonstrate the transformation, transport and fate of pesticides under representative actual use conditions and should substantiate the physicochemical, mobility and biotransformation data garnered from laboratory studies. Environmental fate studies have shown that pesticide dissipation may proceed at different rates under field conditions and may result in degradates forming at levels different from those observed in laboratory studies.

Additionally, products eligible for consideration to control invasive species under an EUP must have some, but not necessarily all, of the following characteristics:

- Low inherent toxicity to non-target organisms. Products with low inherent toxicity to humans and other non-target organisms would be expected to have minimal environmental and health risks even if exposure is extensive.

- Low potential for their use to result in significant human or environmental exposure. When exposure is negligible, risks may be minimal, even if the product has some inherent toxicity;

- Not persistent in the environment;

- Already widely available to the public for other uses, with a history of safe use, under conditions posing equivalent potential for exposure to humans and the environment;

- Pesticidal action that is not the result of toxicity to the target organism (e.g., products that work by attracting, repelling, desiccating or smothering pests); and

- Less likely to select for pest resistance.

Following these guidelines will help ensure protection of human and environmental health when the product is in use under an EUP and allow time to replicate product performance data (laboratory and field) in the U.S. before the product is given a full registration. This may include product label claims for a newly introduced exotic species. Substances with chronic toxicity, genotoxicity, carcinogenicity, neurotoxicity or immunotoxicity, reproductive or developmental toxicity effects, and those that metabolize into compounds of toxicological concern or are anticipated to bioaccumulate are not eligible for review by EPA under this directive.

One suggestion was to make a general statement that allows registration and use of pesticides against exotic invasive species that are yet unknown, but it is difficult to predict which species may enter the U.S. and cause problems in the future. This would permit a quick response with approved pesticides to repress or eradicate these species without having to adapt the guidelines. But it would require a general description of the tests needed in such cases that were logically comparable to the guidelines and relevant for the most closely related group of species. Additionally, a statement would be needed that EPA should be consulted so that it could determine, on a case-by-case basis, the specific testing needs and course of action determined by the set of unique demands of each scenario.

Charge Question 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?

Panel Response - The Panel concluded that grouping of pests taxonomically is appropriate since taxonomy is used in scientific research to categorize and identify taxa and their relationships. However, the Panel noted that pest behavior and biology is also important because habitats where the pests are found and how they behave, directly affect pest management methods. Therefore, alternate ways of grouping pests could take these elements into consideration. For example, one Panel member suggested combining scorpions, centipedes, spiders and cockroaches into one group classified as "crawling insects". Appendix 1, Tables I and II as presented in the TSD lacked details taxonomically, as well as other considerations. This Appendix is an important document since future pesticide considerations may be based on the information it provides. Hence, it needs to be more comprehensive and more detailed in scope. The Panel suggested, in addition to nomenclature, the following three additional categories of pest characteristics be included:

1. **Motility**: The physical activity and behavior of the arthropod (e.g., crawling, jumping, flying, swarming, ectoparasitic, etc.).

2. **Range**: The geographic location(s) where pests are found.

3. **Places of animal/human association**: Where the pests are found that directly affect humans, domesticated animals and native wildlife.

Since taxonomy and systematics, pest activity and pest distributions are continuously changing, it is suggested that Appendix 1 be treated as a living document, and be reexamined and revised as necessary, or on an agreed time schedule. The Panel's suggested revisions of Tables I and II are shown in Appendix 1 of this document and reflect a reviewed compilation of taxa and additional categories drafted by the Panel.

(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)***

Panel Response - Appendix 1: As stated previously, the Panel believed that Appendix 1, Tables I and II require additional details and they suggested some changes to the composition of pest species in the tables. They suggested that EPA consider adding the following insects to Table I: urticating caterpillars, blister beetles (Meloidae), several filth flies, insects of urban concern (i.e., food and clothing insects), several ant species (Formicidae), fruit flies (Drosophilidae), and the Old World screwworm (*Chrysomya bezziana*). Suggested additions are shown in Appendix 1, Table I with green highlighted rows. Insects the Panel suggested might be considered for removal from Appendix 1, Table I are the solitary beneficial pollinators, including the European hornet (*Vespa crabo*), an endangered species, and one species of home invading fly, the cluster fly (*Pollenia rudis*). Those insects suggested for removal are shown in Appendix 1, Table I with red highlighted rows. The Panel questioned whether some species currently in the lists should be included and those are shown with yellow highlighted rows.

As discussed in the response to Charge Question 1, Panel members questioned whether to include veterinary pests since the meeting was convened to address pests of "significant public (human) health importance." During the Panel's revision of Tables I and II, their collective thought progressed to retaining organisms of veterinary significance due to their potential for zoonosis pathogen transmission and physical harm. In fact, they suggested adding several more species (see rows 116-122, Oestridae). Furthermore, it became understood that pests of veterinary concern may directly and/or indirectly affect human health, either by compromising

the health of domestic or non-domestic animals with which humans associate, or as a direct physical attack on humans.

The Panel remained in doubt about the inclusion of a few insects. These include the Argentine ant (*Linepithema humile*). Although it is not perceived to present any human health risk from its presence, it is of concern due to its ability to outcompete native fauna (i.e., other ant species) when introduced to a novel ecosystem. This can cause considerable ripple effect that impacts native food webs. Other insects that the Panel questioned were solitary and beneficial bee species.

Some of the suggested insects for addition, such as the Old World screwworm (*Chrysomya bezziana*), are exotic species not yet introduced to the U.S. These were added because the environments they currently inhabit are similar to certain regions of the U.S. Thus, there is a potential for them to establish populations in North America. Additionally, many of the potentially invading, borderline and troublesome exotic species not specifically identified by genus and species in the tables may be included under the general family or generic spp. categories.

Appendix 5: Most of the Panel members were satisfied with representative test species in Appendix 5, but with some exceptions. One Panel member pointed out that in the EU, scorpions (Group 3), spiders (Group 4, including sub-group 4a) and centipedes (Group 5) are considered under the category "crawling insects" and that, typically, cockroaches (Group 8) (*Blatta germanica*), can be used as representative test insects as they are difficult to control and are available for laboratory tests.

Exceptions and corrections to Appendix 5 pointed out by other Panel members include the following suggestions:

Chiggers - Sub-group 1b

- *Trombicula alfreddugesi* is now renamed *Eutrombicula cinnibars*.

Ticks - Group 2 (including sub-groups 2a, b, and c)

- Suggest adding *Dermacentor andersoni* as a test species as it is easily reared under laboratory conditions and is common.

Spiders - Group 4

- Substitute the brown recluse spider (*Loxosceles recluse*) with another recluse spider species, since the brown recluse is dangerous to work with and there are other safer species in the same genus that would do well in laboratory conditions.

- Add a North American established sac spider species (such as *Cheiracanthium mildei* or *inclusum*) to the Australian test species (*C. mordax*).

- Add Eastern parson spider (*Herpyllus ecclesiasticus*) to Appendix 1, Table 1

Centipedes - Group 5

- Some Panel members remarked that products tested on spiders would also be effective on centipedes. Yet, the general group thought that centipedes should be considered for removal from Appendix 5. Some native species, though capable of inflicting a painful bite (namely the Florida blue centipede, *Hemiscolopendra marginata)*, are, in fact, generally harmless and considered beneficial insects, behaving as active predators of other arthropods within structures.

Fleas - Group 7

- Add the Oriental rat flea (*Xenopsylla cheopis)* as a test species.

Bot flies - Sub-group 9a

- Use G*asterophilus* spp as representative test species instead of listing 3 specific species.

Screwworms - Sub-group 9b

- Note: *Cochliomyia hominivorax* is an eradicated species in the United States.

Flies - Group 10

- Delete Cluster fly (*Pollenia rudis)* as a test species. It was suggested that flies in the genera Fannia be included as a representative test species since they can be relatively easy to rear in laboratory conditions.

Mosquitoes - Group 11

- The Panel suggested having separate tables for killing and repelling and for field and lab testing.
- They questioned suitability of *Culex pipiens* and *quinquefasciatus* in repellent studies.
- Use *Culex* spp. instead of hybrids *C. pipiens* and *C. quinquefasciatus.*
- *Anopheles freeborni* and *punctipennis* are suitable for field testing and not lab testing.
- *Anopheles quadrimaculatus* is not suitable for indoor repellent testing.
- Add *Anopheles albimanus* and *Anopheles stephensi.*
- *Psorophora* is acceptable for field testing.

Horse flies - Sub-group 12a and Deer flies - Sub-group 12b

- The Panel suggested combining into one group

Stable fly - Sub-group 12c

- The Panel suggested that the stable fly (*Stomoxys calcitrans*) and the horn fly (*Haematobia irritans*) be included in the filth fly category (sub-group 10), but they questioned why both species need to be tested.

True bugs - Group 13, Sub-group 13a and 13b

- Test using both species listed under each group and sub-group.

Ants - Group 15

- Add the Tropical fire ant (*Solenopsis geminata*)

Stinging bees, wasps, yellow jackets and hornets - Group 14

- Bald-faced hornet (*Dolichovespula maculata*) is a yellowjacket and should be included under *Vespula* spp.

Carpenter ants - Group 16

- Add the carpenter ant (*Camponotus neracticus*) as a test species. One Panel member suggested having more test species on the list because laboratories may experience hardship obtaining and maintaining colonies of the specific species identified in Appendix 5.
- The Panel questioned the standard "100% prevention of damage to wood" and thought that the lesser 95% would be more acceptable.

Wood-Destroying Beetles - Group 17

- Add true powder-post beetles in the sub-family Lyctinae
- The Panel questioned "100% prevention of damage to wood" and thought that the lesser 95% would be more acceptable.

Termites - Group 18

- Add the drywood termite (*Incisitermes snyderi*)

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

Panel Response - This charge has been largely addressed by the revised tables in Appendix 1 and the aforementioned responses to Charge Questions 1 and 2. The suggestion was made to consider the addition of a stored food and clothing pest group, thus harmonizing with the EU (see Appendix 1, Table I, rows 30 – 31). Though not in the truest sense as direct human health threats, stored product pests can reduce food quality and nutrient levels and be of dermatological and enteric concern. It was also suggested to consider adding a group for urticating caterpillars.

One Panel member suggested the inclusion of live tree pests such as the Asian long-horned beetle (*Anoplophora glabripennis)*, the emerald ash borer (*Agrilus planipennnis)*, as well as other long-horned beetles (Cerambycidae), bark beetles, (sub-family Scolytinae*)*, and jewel beetles (Buprestidae). This would expand on category 2 in the mission statement of the TSD which dealt with "invasive invertebrate species." These have been highlighted in Table II in emerald green. Additionally, the Panel member suggested including fabric infesting moths in the family Tineidae as a representative pest species for Appendix 5.

Charge Question 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?

Panel Response - In addition to the performance standards for public health pests specified in Table 12 of the TSD (percent knockdown, percent mortality, percent repellency and complete protection time (CPT)), the Panel made the following suggestions for additional performance standards in specific cases:

- **Nest kill** - could be added as a criterion for control of social insects such as wasps, ants and termites.

- **Residual activity** - could be a criterion related to CPT, but at a different level; e.g., 90% for termite protection after 3 years. CPT is more associated with 4 hours of protection by a repellent against mosquito biting.

- **Inhibition of development** for eggs and larvae/nymphs.

In Appendix 5 of the TSD, performance standards are provided that show differences between the groups of insects, and the Panel noted a mixed variety of standards ranging from 70 - 100% effect, but for some groups, no minimal performance standards were given. Some minimal performance standards were included in the Product Performance Test Guidelines 810.3000-3800, but not in 810.3500, 810.3600 and 810.3700. Each of the insect groups need a separate table with performance standards.

The 95% performance standards proposed in Table 12 are much too general to be applicable in all situations and the note below the table, in regard to mites, indicated this. Performance standards should be specified per group of insects and per intended use. The Panel suggested the general standard of 95% could be used in case no other specific standards are established.

The performance thresholds were fine for laboratory studies, or even simulated field studies where most of the parameters can be controlled. In some field studies, particularly those with insects that develop rapidly and have overlapping generations, it would be more difficult to measure longer term control or kill following an application by solely surveying or monitoring a population because mortality might be offset by numbers of arthropods entering the population through emergence or dispersal. Some thought should be given to these types of field studies with guidance on how to correctly measure insecticide effects.

The definition for control contains the term "residual." This is somewhat ambiguous as residual can mean mortality that is unexplained or the length of time a product is active. The Panel suspected it means kill during a specific period of time. In fact, in all of the definitions, the time component is really undefined except for calculations that were made before and after an application. The length of time after an application, either directly or in the environment, should be specified. This could also be made relative to the appearance of the damaging stage (e.g., adults and/or larvae). It could also be defined in terms of the number of applications or feedings. If mortality with a single feeding is 0.78, or 78%, then mortality after two feedings is 1 - (1-.78)*(1-.78) = .95 or 95%.

The EU typically does not specify a fixed level of kill or control for a performance standard. The EU conventions often use 90%, or allow 90% when 100% was specified, but not achieved. The EU prefers the idea of specifying mortality of X % within a specified time period. Additionally, dose and application frequency can trump the mortality or control claims. Keeping some populations below a problem threshold is enough; this might be done with lower levels of mortality. In the case of face fly, most products do not give 90% control and raising the performance standard for them would eliminate most products on the market. Users are generally satisfied with less than 80% control and tend to be mainly concerned about reduction in the number of cases of pinkeye, a disease transmitted by face fly. This does not require the high levels of control proposed 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?

Panel Response - The Panel stated that product performance is not always measured in terms of kill or population reduction. While these metrics are very valid, the key measure of performance is in terms of the degree of protection from damage, and this may or may not necessarily be dependent on arthropod population size. In a number of instances, especially where damage occurs through "nuisance," the target's tolerance for the pest plays a tremendous role in defining what levels of annoyance are acceptable. In some instances, 50% reduction may be enough to

prevent a nuisance problem; in others, a 95% reduction may have little effect in preventing a nuisance problem.

For scabies and demodex mites, as well as other ectoparasites, population assessments are difficult and not necessarily 100% accurate or even detectable. The smaller an infestation is, the more difficult it is to detect. There may be some low infestation level with a high probability that, even though the mite is present, it will not be detected. This can give a false impression of complete control. Also, sampling for mite detection involves invasive skin scrapings which can be problematic. Perhaps a better measure of efficacy is the time to alleviate symptoms; e.g., reduce itching, rashes, etc. The addition of morbidity might be a good idea as these arthropods are removed from the host population.

Lastly, some thought should be given to expressing control for arthropod populations measured by using ordinal or ranking scales. In these cases, ranges of levels of pest density are given some arbitrary scale due to difficulty in accurately counting numbers (e.g., 0 mites = 0; 1 – 10 mites = 1; 11 – 100 mites = 2; etc.). This methodology is commonly used with mites, lice, and flies. Even binomial scales can be used. In these cases, calculation of means and percent reductions are not meaningful, but they still provide very useful data since users can be concerned only with the question of whether they have a little or a lot of the pest.

There are alternative performance standards available. An overview of the EPA and EU standard performance levels for the different groups of insects and mites is provided in Appendix 2.

In summary, the Panel made the following general conclusions:

- A standard performance level of 95% for all uses and all groups is not advisable.
- The different performance standards in the different guidance documents are confusing.
- There is currently no complete set of guidance documents; there are some on the species level, others on premises, buildings or wood.
- Advise having one logical complete set of guidance documents that include performance standards that cover the whole field of use, preferably based on insect groups or otherwise on targets.
- Standard performance levels should be decided for each combination of product types (baits, preventive treatments, curative treatments, IGRs, repellents, etc.), group of arthropods to be controlled, and treated object.
- All combinations of product types not covered by established specific performance levels should have a general standard performance level, such as 95 - 100% kill in the laboratory and 90 - 95% kill in the field.
- EPA should have the authority to overrule the performance standards in special cases, if proper justification is provided by the applicant(s) about why the standards are not deemed applicable to a certain product.

Charge Question 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.

Panel Response - The Panel was asked if some of the testing parameters in guideline 810.3700 should be described with greater specificity for consistent and reliable estimates of CPT for product label claims. The Panel made the following suggestions for specific sections of the guideline that could improve estimation of CPT for purposes of product label claims.

Paragraph (b)(1)(iv): - "A crossing may be quantified either or both by the distance the tick or chigger moves onto treated skin or by how long the tick or chigger remains on treated skin."

The Panel questioned whether the actions described in this statement are measuring the same thing. If not, allowing both to be an outcome of a test would confound the product labeling effort. Does the individual conducting the test decide? How does the statement account for a crossing, but then a drop off? The Panel recommended choosing one or the other as a measurable outcome to provide greater clarity to registrants.

Paragraph (c)(1)(iii)(A): Dose determination

In the guideline description of "dose determination," the Panel believed use of the words "multiple applications" is rather vague. A power analysis conducted by the registrant or at least a minimum number of subjects specified by EPA was suggested. The typical dose or "dosimetry" is the average application rate by consumers (test subjects) on themselves. There may be an opportunity for bias if consumers feel they must meet a certain expectation when doing the applications. Also, an application in an efficacy study (e.g., preparing for a field trial) may not accurately reflect what someone might really apply to themselves if they are anticipating an activity such as hiking, hunting or other outdoor activity when arthropod contact might be high.

Paragraph (c)(1)(iii)(B): Repellency

While it was made clear during the overview that EPA is not currently considering revision of guideline 810.3700 (it was last revised in 2010), the charge question as put forth to the Panel, particularly parts (a) and (b), led the Panel to infer that recommendations on changes to the guideline should be addressed. Thus, in the interest of transparency and to provide a comprehensive answer to the charge question, the use of CPT will be addressed. Using the EPA definition of CPT ("the time from application of a repellent until efficacy failure, as defined in the protocol used to conduct the study"), a repellent would fail at the point in time when one mosquito bites or one tick crosses a line, or by successive bites or crossings within a 30 minute period. The CPT will likely underestimate repellency and use of CPT as a criterion for evaluating repellent efficacy may encourage the over-application of repellents because consumers may believe that they would be vulnerable to attack after the CPT period.

Measuring percent repellency with 95% as the minimum allowable in estimating protection time for repellents applied to skin would likely yield more reliable results. A requirement of 100% repellency is too rigorous because it does not take into account the size of the mosquito population and intensity of activity. Using 95% reduction in landing or biting is a more appropriate measure of the response of a mosquito test population as a whole in

comparison to CPT. CPT essentially records the activity of outliers and provides the time when the first outlier lands (or bites) or the landing (biting) followed by a landing (bite) of a second outlier. What would the CPT be for a repellent that achieved 99% repellency at 1 hour, 100% at 1.5 hours, and 99% at 2 hours?

If landings were allowed (or bites or crossings), then why not use percent repellency as the measure instead? EPA allows the study design to use either landing or bites, but then goes on to strongly recommend landings. The Panel recommended not offering a choice. When would measuring "bites" be justified, according to EPA? Furthermore, use of landing rather than biting as an endpoint in repellent tests would require formulators to increase the volatility of their formulations to increase the repellent activity of their end use products. Increased volatility would decrease CPT unless the concentration of the active ingredient was increased. Some, if not most, repellents work as a contact irritant rather than a spatial repellent (altering seeking behavior). Therefore, landing as an endpoint should be defined in terms of a "touch time" such as greater than 2 seconds rather than as a simple touch with immediate lift off. Use of biting as an endpoint must be carefully considered for field studies due to risk of disease transmission to volunteers.

The Panel agreed that from a consumer perspective, when reading a product label, it is more likely that the average consumer would understand repellency when stated in terms of CPT rather than as "percent repellency over time". However, duration of percent repellency could be written on a product label in a common sense way to enhance understanding by a consumer.

Paragraph (c)(1)(v): Sample size

The Panel believed that the only way that a median CPT can be estimated was with multiple study participants and, therefore, the emphasis should be on replication of study participants within each lab or field trial. They recommended that a statistician be consulted for protocol submission and that it include a power analysis.

Paragraph (i): Specific guidance for dose-determination studies

Guideline 810.3700 states that for testing DEET (N,N-diethyl-meta-toluamide) lotion formulations, the standard dose was 1 g per 600 cm^2. The guideline stated only that this was through many tests of repellency; therefore, it was not clear how the dose was determined. Has this been established over time, as a "typical consumer dose," using methods described by EPA? If so, the guideline should include a description or clarification. Why would this dose not also be a standard for other active ingredients? The only reason given was that no comparable standard dose had been identified. When was the standard dose for DEET identified by EPA? In public comments made by the DEET Task Force, it was noted that variable dosing would have an impact on CPT. This could lead to an overestimation or underestimation of CPT, which may provide inaccurate information to the consumer for protection against a public health pest and could complicate EPA's efforts to begin a repellent mark/graphic program. Data should be easily comparable across studies, registrants, etc.

Paragraph (i)(4): Methods

The Panel recommended that EPA establish the dose for spray-type formulations.

Paragraph (j)(1): Species (in lab studies)

EPA specifies which mosquito species should be used for conducting laboratory studies. However, this does not agree with the recommendations proposed in Appendix 5 of the TSD. The Panel recommended that guideline 810.3700 be revised to reflect the Panel's recommendations to Appendix 5 (for mosquitoes) that EPA chooses to accept (e.g., differentiating between field and laboratory studies, repellent requirements versus other types of pesticides).

Paragraph (j)(10): Untreated controls

One or two untreated persons are used to verify landing pressure in CPT tests. This is not a true negative control because untreated persons are not to be compared to treated persons. The Panel recommended clarification. Further, multiple negative controls are required for studies of relative protection or percent repellency. If the Agency uses CPT as the endpoint or measure of repellency (which is not recommended), it creates confusion or ambiguity in the guidelines for registrants. This comment also applies to other places in the guidelines that describe "untreated controls".

Paragraph (k)(2): Choice of field testing sites

EPA recommended two distinct habitats for field testing sites where the predominant mosquito species differ, but it did not provide any specific guidance on what species should be targeted for these field studies. A registrant must provide field data (which EPA prefers) to support a product label claim against mosquitoes; however, field data on some of the specific species identified in Appendix 5 of the TSD could not readily be obtained in the U.S. Any adopted "test requirements" from the TSD should be harmonized with preexisting published guidelines.

Paragraph (k)(10): Test subject placement and behavior

The guideline states "subjects may work in pairs.....;" however, working in pairs would likely interfere with a true measurement on the actual test subject for many reasons. A second person acting as "collector" would create an additional attractant (if not wearing repellent) or repellent (if required to wear repellent to minimize risk). It is entirely possible to adequately train test subjects to use an aspirator and collecting cup prior to execution of a field study thus eliminating the need to work in pairs.

In Unit VII, Part A of the TSD, EPA stated that they are planning to implement a voluntary repellency mark program and that information derived from this SAP may be used to further refine the criteria for this voluntary program. Registrants would have to demonstrate CPT $\geq$ 2 hours (the current endpoint or measurement for efficacy) in order to use a proposed

graphic or repellency mark on a product label. In Table 12 of the TSD, EPA states that a CPT $\geq$ 2 hours would be required for any repellent, implying a minimum standard for registration. This does not entirely agree with the statements in Unit VII Part A, which is likely an oversight, but should be made clear by EPA. The Panel inquired whether a CPT $\geq$ 2 hours is required for registration of a repellent product or merely required to use the voluntary graphic on labels. The Panel thought that EPA's concept for the repellency mark program was a good idea since it aims to help consumers by reflecting protection times supported by data generated through performance testing and they thought that it should ultimately be a mandatory program.

A Panel member noted that there is a discussion in the EU concerning protection times and the current line of thought is to work with average protection times because there can be large differences in responses between tested individuals. EPA's proposal to put whole hours of protection time on a product label would require calculation of the average protection time. Due to the high variability in individual protection time, the 100% criterion cannot be applied as the only criterion for the derivation of the protection time. If all users are to be protected at 100% during a claimed period, the protection time on the label would need to be very low. The Panel members, therefore, suggested deriving a mean value to use as the protection time on a product label. It should somehow be stated on the product label that the declared hours of protection represent a mean value (e.g., "protects on average X hours"). For the calculation of the mean value, the EU uses only those studies which fulfill the requirements of the official guidelines (EPA, WHO) and which were conducted with at least 10 test persons. If test methods deviate from official guidelines and are less rigorous, the labeling should be adjusted, for example, by subtracting a certain amount of declared hours (e.g., 5 instead of 6 hours).

(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?

Panel Response - The Panel believed that if the goal of EPA is to create a system whereby a standard label could be applied to repellent product labels, then the data that is generated by registrants must be comparable. The guidelines currently allow registrants flexibility in most of the testing methods and in measuring outcomes. EPA requires field studies which have inherent variation due to abiotic factors that are difficult to control. Allowing flexibility in testing methods and how outcomes are measured introduces more variability and makes it more difficult to reasonably compare field studies between different products. It was noted that the DEET task force adamantly opposed the use of the repellency mark, citing inconsistencies in data collection techniques and different field conditions. The DEET task force also went on to state that it was not possible to compare data between field studies because of differing environmental conditions. The Panel did not believe this is necessarily true. While abiotic factors are difficult to control, standard performance testing methods will eliminate other types of variability and it is completely feasible to be able to compare results from field tests that have standard testing methodologies.

In general, the Panel concluded that the following components of product performance testing were important to sufficiently demonstrate a performance standard:

- Further defining "crossing" for tick testing.
- Establishing the dose used across all repellent studies rather than allowing flexibility in determining the typical consumer dose.
- Outcome or measurement of repellency should be the same across studies in order to create a database of results that are comparable. Allowing flexibility in landing versus bite versus probe will result in data that cannot be compared.
- Sample size is critical. Power analysis is the best way to ensure there are adequate numbers of replicates.
- Positive and negative controls are also essential.
- Sample size and controls are basic elements of good experimental design and should be employed.

If CPT is to be used, a minimum CPT of 2 hours was suggested by the Panel as a minimal criterion for product registration, not just for allowing the use of a graphic on a product label. A repellent of shorter duration may not provide sufficient, useful protection in practical terms and will give consumers a false sense of protection.

EPA's consideration of requiring efficacy data for 25(b) repellents is a step in the right direction. EPA's mission is to ensure that consumers are protected, and in this case, protected against potential vectors of disease. It is remiss to allow certain products with a 25(b) active ingredient, particularly those intended to repel arthropods that have the potential to transmit diseases, to enter the marketplace exempt from product performance testing requirements. EPA should take a proactive and visible stance in this area to reduce consumer misinformation.

(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?

Panel Response - The Panel believed that use of the whole number is realistic for expressing CPT, but asked whether the CPT would be rounded up or down. Standard rounding conventions would lead to an overestimation of CPT when numbers are rounded up. Therefore, the Panel recommended rounding numbers down.

A typical statement on a product label might read, "This product protects for an average period of 6 hours from biting mosquitoes." One Panel member did not think such a statement provided useful information to consumers. In parts of the EU, there are only *Culex* species, but many consumers take DEET products with them on vacations to the tropics. Therefore, the EU has adopted label instructions that say: "This product protects for an average period of 6 hours

from biting mosquitoes in the Netherlands, for an average period of 3 hours against yellow fever mosquitoes and 5 hours against malaria mosquitoes." This provides more useful information to a consumer. A CPT would reduce the claimed protection time while in practice the product may be effective for a longer period.

It was also suggested that consumer activity and behavior be part of labeling considerations and the Panel asked if there should there be something on the product label that differentiates between types of consumer activities. EPA responded that some companies are already making this distinction on their product packaging.

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

Panel Response - One Panel member recommended using different CPTs on the product label for different mosquito species. In general, *Aedes* are the most aggressive species, and have a much shorter CPT than *Culex* species. *Anopheles* is between *Aedes* spp. and *Culex* spp. with regard to aggressive feeding behavior. Depending on the climatic zone and country, different mosquito species may be present and different CPTs may be relevant. Are consumers aware that there are different mosquito species at "home" or when traveling? It was suggested that a map indicating regions with different mosquito species using different colors could be useful.

For research on mosquitoes, the Panel suggested using a set number of mosquitoes per cm^3 rather than requiring a specific cage size. This would provide some flexibility for laboratories with different levels of resources.

The Panel noted that there are other testing methods that might be more realistic for ticks and/or chiggers, and suggested that they be considered for use (Witting-Bissinger et al., 2008; Carroll et al., 2010; Dautel, 2004; Pretorious et al., 2003; Jensenius et al., 2005).

One Panel member suggested that evaluation of spatial repellents (e.g., coils, candles, clip-ons) and barrier sprays, while not skin repellents, could include animal baited traps for outdoor studies as a model that would not use humans. These types of products are not covered under the current guidelines.

Charge Question 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.

Panel Response -

Guideline 810.3000 General considerations for Efficacy of Invertebrate control agents

The Panel concluded that Guideline 810.3000 was not very informative as currently written. Because other guidelines do not cover all arthropod species nor all areas of use, there is a need for a general guideline document for all products and their uses that may not be covered by specific guidelines. The Panel suggested incorporating information, definitions, considerations and decisions cited in the TSD and recommendations from the Panel into this general guideline so that it covers any type of product that is not covered by the specific guidelines 810.3100-3800. This general guideline could also contain a table with all the performance standards for the different groups of pests and product uses. It might additionally contain a list of specific guidelines, a list of commonly used and accepted test procedures and literature references. Such a revision would make Guideline 810.3000 the primary document covering all other specific guidelines for this group of products.

OPPTS Guidelines 810.3100-3600

The TSD indicated that Guidelines 810.3100-3600 should: (1) provide specific guidance on testing methods; (2) present examples of protocols that are considered acceptable by EPA for generating product performance data to support product registration (these protocols should be specific to laboratory and/or small scale simulated use and/or large scale studies under

operational conditions as intended by a product label); (3) include substantiation of product label claims; and (4) each guideline should include an appropriate list of pests that could be tested using the guideline and a consideration of international protocols, when appropriate. These suggestions by EPA were supported by the SAP, but the Panel further suggested adding the following: (5) considerations on resistance development; (6) minimum performance standards may have to be adapted and specified; and (7) include requirements or protocol standards for laboratory tests, simulated use tests and field tests. The Panel suggested that these seven general improvements be applied to each of the following guidelines along with the specific recommendations below.

Guideline 810.3100 - Soil treatment for Imported Fire Ants

Guideline 810.3100 currently describes only two pesticide applications, broadcast and mound treatment. Bait products should be included with test protocols on palatability, choice and no-choice testing and transfer of baits. The Panel recommended other ant species be included in this guideline, such as the pharaoh ant (*Monomorium pharaonis*), Argentine ant (*Linepithema humile*), odorous house ant (*Tapinoma sessile*), and harvester ant (*Pogonomyrmex* spp.). Furthermore, the Panel agreed that this guideline should be renamed as proposed in the TSD on page 24 to represent a broader category of ants rather than only imported fire ants (*Solenopsis* spp.).

Guideline 810.3200 - Livestock, Poultry, Fur- and Wool-bearing Animal Treatments

The TSD (page 24) proposed restricting the content of this guideline to livestock (beef and/or dairy cattle, pigs, and sheep) and horses. The proposed restriction would exclude chickens, turkeys and fur-bearing animals. The Panel did not know the reasons for this restriction. Thus, the heading "livestock" might include other domesticated agricultural animals, such as goats. For chickens and other domestic fowl, only the control of fly larvae was described, but ticks, mites, lice and mosquitoes also attack them and may need to be controlled. Additionally, there were no specific control measurements or performance standards for fur- and wool-bearing animals at all. Test protocols and performance standards against pests of domestic fowl and fur- and wool-bearing animals should be added, or included in one or two new separate guidance documents. It may be useful to differentiate between commercial and amateur livestock keeping/activities, as well as size of the operations. The products that are allowed for both groups of users may differ, as well as the use instructions on a product label. In general, it is believed that professionals have had training in the use of pesticides and arthropod resistance management, and thus should be more capable of dealing with restricted products, difficult to control pests and complicated procedures.

Guideline 810.3300 - Treatments to Control Pests of Humans and Pets

The TSD (page 24) proposed "to restrict the content to products applied to pets (dogs and cats), such as spot-ons, shampoos, and collars," and to "move pests of humans to other guidelines as appropriate." The species that attack humans and pets may be slightly different, but these groups, their behaviour, pesticides used and control methods are very similar. The Panel believed that there was no reason to separate the guidance documents for humans and pets.

There can be borderline issues with medical and veterinary pesticide products and this may be a reason to separate the use for humans and pets, but for efficacy alone, the Panel saw no reasons to do this. It was interesting to note that for humans, generally 100% kill was advocated, whereas for pets, 90% was sufficient.

Guideline 810.3400 - Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments

The TSD (page 24) proposed to "Rename to include Mosquitoes and Biting Flies." The Panel found it a good idea to make this guideline more general to include all species of arthropods that attack humans, their pets and livestock. In this respect, this guideline, which mainly concerns flying insects, might be combined with the previously discussed guideline 810.3300 which deals mainly with crawling insects. This would make a difference in the products used, test protocols and performance standards because of the different groups of arthropods and their life histories. In general, it would be advisable to structure the guidelines into a logical grouping that covers a set of guidance documents either based on types of arthropods or on use in certain situations. The present set of guidelines is a mix of both and does not cover all situations or arthropod species. In addition, these guidelines were not written in a logical manner and may be confusing to product registration applicants and the public.

Guideline 810.3500 - Premise Treatments

The TSD (page 24) proposed a "Complete revision with guidance and protocols for crawling and flying insects." The Panel agreed with the idea of revising this guideline and suggested that the title be more specific with reference to crawling and flying insect pests of public health importance. However, the Panel suggested that the title revision would also be too general and it should include mosquito and biting flies; thus, it would then overlap with Guideline 810.3400. One option would be to combine these two guidelines. Furthermore, specific remarks by the Panel for consideration were the following: the guideline could include a test for sprays against general crawling insects; often cockroaches are used as the test animal because they are difficult to kill and are easy to raise in laboratory settings; porous concrete can be used as a worst case substrate; a list of species to be controlled should be added because the guideline is now very general; and spatial treatment could be added.

Guideline 810.3600 - Structural Treatments

The TSD proposes the following revisions:

- Add complete description of USDA-FS laboratory and field protocols for soil-applied termiticide testing.

- Consider adding protocols for testing exterior perimeter treatments that include modifications to soil treatments including depth of treatment, rodding and trenching, and amount of finished dilution delivered per unit area.

- Address testing of wood-destroying insects other than termites

The Panel agreed with EPA suggestions to revise this guideline (TSD, page 25), but further suggested the inclusion of all termite control products, such as termite baits, which are currently in Guideline 810.3800.

During the public comment period, the Consumer Specialty Products Association (CSPA) suggested that the established guidelines need to be more explicit regarding the testing, tracking more closely to a pre-set protocol of demonstrated needs. For example, proposed updated product performance guidelines for premise treatments were submitted to EPA by the CSPA in 2010 and the Panel suggested that these be consulted for guidance as EPA updates the current guidelines.

In summary, the Panel concluded that the whole set of guidelines needs to be revised and updated with the addition of more information, standard procedures, performance standards and test protocols. Also, there needs to be a rewriting of material between the pre-existing guidelines and new guidelines developing a complete set of logically directed guidelines that cover all arthropods that impact human health, their structures and possessions, pets and domesticated livestock. As an example, one suggestion was to use the arthropod groupings shown in Table 1 below. The scope could be pests in the direct human environment grouped into four categories: 1) ectoparasites (mites, ticks, fleas and lice), 2) crawling arthropods (scorpions, spiders, centipedes and cockroaches), 3) stinging and biting arthropods and 4) wood-destroying insects. Alternatively, another example of grouping the pests is to develop four guidelines for: 1) pests of humans, 2) their buildings/structures, 3) their possessions and 4) their pets and domestic animals. Other groupings are also possible as long as pesticide use and all the pest groups are logically covered with clear and updated guidelines.

Table 1. Categories of Pests and Categories of Targets for Use of Pesticides.

Pest group	Humans	House pets and farmyard animals	Buildings	Possessions (food, stored products, cloths)
Ectoparasites (Mites, ticks, fleas and lice)	X	X	X	X
Crawling insects (scorpions, spiders, centipedes and cockroaches)	X	X	X	X
Stinging and biting insects (flies, bugs, mosquitoes, wasps, bees and ants)	X	X	X	X
Wood-destroying insects (carpenter ants, termites and wood boring beetles)			X	

(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?

Panel Response - The Panel believed that there are a number of international guidelines that are worthy of adoption or to use as a basis to improve or modify current EPA guidelines. These international guidelines include the following:

- **WHO** – The World Health Organization has useful test protocols for mosquito control and repellency.
- **OECD** – The Organization for Economic Cooperation and Development works mainly on crop protection products, but recently started developing guidelines for other groups of products. There is a useful cockroach guideline and a guideline for bed bugs being developed.
- **EU** – The European Union efficacy guideline PT18/19 covers insecticides, acaricides and

products to control other arthropods. The document includes all non-crop pesticides used in the EU along with most arthropod species groups discussed in this SAP meeting except for lice and mites that fall under medical and veterinary guidelines.

- **EU** Technical Notes for Guidance (TNsG) addresses efficacy evaluation of wood preservative biocidal products and it contains useful guidelines for efficacy data on wood boring beetles, termites and marine borers, such as mussels and crustaceans.
- **FAO** – The Food and Agriculture Organization mainly deals with crop protection products, but their useful guidelines are worth considering.
- **EPPO** – The European and Mediterranean Plant Protection Organization works mainly with crop protection products, but their useful guidelines are also worth considering.

In their public comments, the CSPA stated "it would not be prudent to harmonize or use international efficacy guidelines. The EU does not consider U.S. data when registering products and the current EU Biocides Directive—soon to be replaced by the Biocides Regulation, has proven to be a slow, tedious process without proven results. EPA and registrants have the most experience with U.S. pests, data generated to support registration of pesticides that target them, and the wide-ranging environments in which the pesticides must be used. This experience should not be abandoned or diminished; EPA and the registrants are best situated to handle data generation in the United States." The Panel indicated that if arthropod species are the same or very similar, the EU will accept U.S. data. Also, tests done according to EPA and other accepted test protocols are accepted by the EU. Much can be gained from other organizations' methods and standards. Addressing test arthropod species differences may be more challenging, but in a number of identified groups in this document, species are identical or very similar at the sub-species level (mosquitoes, ants, lice, fleas, wood boring beetles, etc.). Mutual international/inter-agency acceptance and agreement in the selection of specific test arthropod species is realistic.

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

Panel Response - The Panel advised EPA to gather all available data from international organizations, public literature, companies and stakeholder organizations (such as those whom commented for this SAP meeting) when revising the (older) guidelines. Considering already developed and tested guidelines from government agencies from around the world is advisable. Test designs and protocols may also have been developed by institutions of learning (universities, etc.) and research organizations, and it was suggested that these be consulted. Industry test procedures may be a useful source as well. The Panel suggested that recognized experts in particular target groups of arthropods and/or specific species identified in the new guidelines should be consulted to further improve the veracity of this review.

Charge Question 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?

Panel Response - There was unanimous agreement among the Panel that data collected using the technical active ingredient alone was not sufficient to support the efficacy of an end use product. The activity of a formulated pesticide can be affected by other chemicals and materials that are contained in the end product formulation. In many instances these materials enhance the active ingredient (e.g., extending release time or protecting the active ingredient so it might last longer) so that less amount of active ingredient might be needed in a final formulation.

(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?

Panel Response - The majority of the Panel thought that in order to characterize the efficacy of an end use product formulation, dose-response data on that formulation was needed, but not dose-response data for the active ingredient. A minority opinion was that dose-response data on the active ingredient should also be provided. The Panel noted that companies should be conducting primary screening assays to establish the relationship between the concentrations of the active ingredient and arthropod mortality. The Panel also noted that without dose-response data for the active ingredient, interactions (e.g., synergism versus additive effects) between the active ingredient and other components of the formulation are impossible to discern.

(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)?

Panel Response - The Panel unanimously agreed that the efficacy of formulated products for a given active ingredient should be established in separate laboratory bioassays or field experiments because it can vary among different formulations of the same active ingredient. In other words, the ingredients of a formulation can have profound effects on how it performs. If the difference in formulation is simply more or less of an active ingredient (assuming all other ingredients are the same and in the same relative amounts), then testing of the additional formulations might not be necessary. Emphasis here is on "might not be necessary." For example, in the case of repellents, less active ingredient does not mean the product repels less effectively, but that it might not repel for as long a period of time. Data from the two products would be needed to support the different repellency times claimed. In their comments, the

Association of Structural Pest Control Regulatory Officials (ASPCRO) gave a good example with so called non-repellent termiticides where changing an emulsifier or inert ingredient can change the repellency effect or response behavior of the pest, thus changing the performance outcome of the product.

One Panel member commented that minor changes in the formulation with no effect on efficacy can be accepted if proper justification is provided. A reference test (laboratory or simulated use test) with the two products showing very similar effects at the same use concentration may be required.

(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?

Panel Response – The Panel unanimously agreed that having data on the efficacy of each active ingredient would be informative, but these data would not be sufficient to understand the efficacy of end use products containing multiple active ingredients. Data on the efficacy of the blended end use product is needed. In other words, products with multiple active ingredients should each have their own set of data since the mixing of several active ingredients can result in synergism and affect the efficacy of the end use product.

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

Panel Response - There were differences of opinion among the Panel members in response to this question. Some believed that minimum effective doses may be required of end use products that are meant to be used in different habitats, particularly out of doors, so that the lowest dose that will give consistent results for a reasonable range of conditions can be determined. Others believed that if a product is effective at a specified application rate, it is not essential for the end user to know how little can be applied to have a treatment failure.

One Panel member stated that minimum effective dose is needed because it is not desirable to use too much product for environmental reasons nor should there be under-dosing because of resistance development concerns.

(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?

Panel Response - The Panel agreed that a discriminating dose is usually derived from dose-response data. A discriminating dose is suitable for differentiating insecticide susceptible and resistant populations of target arthropod species. Dose-response bioassays are the best method of evaluating the susceptibility of any given arthropod species to an insecticide and for comparing the susceptibility of different geographic populations of the same species. With repellents, it is the duration of repellency as measured by protection time that is important. However, determination of a discriminating dose may be appropriate if a claim of "kills resistant pests" is

made. Furthermore, the frequency of application and length of exposure are important parameters to consider in evaluating the effectiveness of an insecticide or repellent.

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

Panel Response - In general, the guidance provided is adequate. Under test species name, some information on the history of laboratory colonies should also be provided. Under experimental conditions, time of testing and length of the experimental period should be included. Circadian rhythms can influence intrinsic arthropod responses to toxicants. A different set of parameters may need to be recorded for field studies versus laboratory studies (e.g., range of temperature during the experiment, wind speed and humidity, etc.). ASPCRO expresses a valid concept that when conducting some field testing, residents (people living in a dwelling being tested) cannot be excluded from the study site, which may violate GLP protocols. Some mechanism for study protocol flexibility may be appropriate.

One Panel member stated that batch number and production date may be useful to add to test materials. This can be very useful information for both for the applicant as well as for the evaluator.

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

Panel Response - For mosquitocides, the guidelines are adequate for laboratory testing. However, for field testing, examples of additional parameters that need to be documented should be added. For example, trap types, trap location descriptions and additional weather data are needed. The Panel believed that EPA should consider convening a separate panel to address this important question.

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

Panel Response - The Panel believed that well-controlled laboratory assays should be required for repellent testing. Laboratory bioassays should be designed to rigorously test the formulated product under standardized conditions so that the consumer can rely on product label claims to make an informed decision in selecting a product. Field conditions cannot be controlled. Field studies should be conducted to verify laboratory study results. EPA should consider requesting information on the residual and shelf life of some end use products. One Panel member stated that residual effects and shelf life can realize a 10% loss of activity over a period of 6-12 months.

There was discussion about whether the requirement that data be collected under GLP would exert an undue burden on private companies and university researchers who perform contractual insecticide testing. The Panel suggested as an alternative that some form of third party quality assurance inspection (e.g., ISO 9000 series audit) of data collected for end use product registration be considered. The Panel believed that this would strengthen the quality of data collected and promote public trust in the performance of end use products.

Charge Question 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) – The Panel reported that the speed of intoxication for various active ingredients for termites and cockroaches is as follows: pyrethroids > organophophates > fipronil > neonicotinoids = avermectins (gaba inhibitors) ≥ hydramethylnon (inhibitor of cellular respiration) > borates > chitin synthesis inhibitors ≥ juvenoids.

For (a) mode of action of the active ingredients, (b) formulation type and (c) pest group and life stage, the Panel recommended that a pilot study should be run to find out in what universe the molecule/formulation performs. Plate tests, time to kill, timed exposure, lethal dose, lethal time, lethal concentration, etc. do not predict the performance (i.e., percent effect) in field trials. Almost always (except for Peet-Grady type bioassays), the predictive tests in the laboratory for field performance are tweaked versions of choice tests (Ebeling's choice box or some other arena test), giving a test organism the opportunity not to die if it possesses the ability to avoid a toxicant. In reference to field tests for cockroach baits, comments submitted by S.C. Johnson indicated the success of German cockroach baits that were developed using arena tests.

The Panel did not believe that the mode of action of the toxicant is critical to the development of the assay. The same assay involving forced contact with residues of an active ingredient that penetrates the arthropod's cuticle could be used for crawling pests, regardless of whether an active ingredient acts as an insect growth regulator or blocks the sodium channel. For some microbial pesticides (e.g., various *Bacillus thuringiensis* strains) or toxic baits that have to be ingested, the assay would need to involve consumption of the active ingredient. Accordingly, the assay should reflect the mode of exposure to the toxicant under field operational conditions.

(b) Formulation type – The Panel reported that exposure time required for different formulations is as follows: emulsifiable concentrates > wettable powder ≥ dust = microencapsulation > solvent systems. The formulation type needs to be matched to the mode of exposure of the arthropod and the longevity requirement of the treatment. For example, to be effective, toxic baits must be ingested by cockroaches; therefore, forcing cockroaches into contact with the toxic bait would not be a suitable means of determining the efficacy of the bait. Mosquito larvicides are applied to water; therefore, the active ingredients are either ingested or penetrate the larval cuticle. Assays for different types of formulations need to be developed based on the mode of larval exposure.

(c) Pest group and life stage – The Panel indicated that, in general, the amount of active ingredient required to kill different life stages is as follows: pupae > adult female = large nymphs > adult male > small nymphs. Plate tests, time to kill, timed exposure, lethal dose, lethal time, lethal concentration, etc., do not predict the performance (i.e., percent effect) in the field. The habitat and behavior of the arthropod life stage is critical to assay development. For example, for mosquito control, adulticides should be tested as aerosol sprays for products that are applied as ultra-low volume sprays or as residues inside glass bottles to mimic indoor (building/structural) residual treatments.

(d) Surface types – The Panel indicated that the amount of active ingredient deposit required for intoxication on various surface types is as follows: stainless steel = glass < linoleum < painted wood < wood. Also, sand < high organic soil = clay soil. Again, it depends on the target arthropod's habitat and behavior. For example, formulated products for termite control may be tested after incorporation into soil or applied to the surface of wood. Mosquito larvicides would be applied to the surface of water.

(e) Forced exposure test compared to a choice test - Forced exposure will reveal the intrinsic susceptibility of an arthropod to the active ingredient. A choice test will reveal any repellent characteristics of the formulated product or behavior avoidance by the target arthropod. With the German cockroach, for example, most insecticides are ineffective in choice tests, but highly effective in forced exposure.

(f) Length of exposure time - A foraging German cockroach will avoid residuals of most insecticides given the option to avoid the residue. Therefore, exposure time in a plate test with the objective to simulate a field event would be a very short (seconds) exposure time. This is why the choice box is a better insecticide/German cockroach evaluation protocol to predict field performance. A suggested reference contained in a comment submitted by ASPCO/NPMA Efficacy Workgroup (Attachment 3 bed bug recommendations - 10/13/2011) indicated that bed bugs will not try to avoid pyrethroid treatments (Moor and Miller, 2006). This depends in part on the toxicity of the formulated product and mode of exposure. Some toxicants gain entry into arthropods quickly so the exposure period could be relatively short. For example, mosquito adulticides are often tested by forcing adult mosquitoes into contact with insecticide residues on the surface of glass bottles or treated papers for one hour and then they are transferred to an untreated container and mortality observed 24 hours later.

(g) Length of post-exposure evaluation period - Periodic readings are necessary (every several minutes, then every hour, then every few hours, then overnight, 1 day or 2 days, etc.) until an end point is reached for residual surface treatment efficacy. The length of post-exposure evaluation period will depend on the length of time protection is required. For example, termiticides need to be tested over a long period of time (months to years), while products for head lice control could be evaluated over a shorter period of time (hours, days to weeks).

(h) Age of surface residues - Intoxication activity decreases over time until it breaks down or an end point of termination has been achieved. The age of surface residues will also depend on the length of time of the protection period. Soil or wood treated with termiticides need to be tested for bioactivity over a very long period of time that reflects the length of time protection is

needed. Indoor residual sprays of insecticides should be active for weeks to months after application. Assays of bioactivity should be designed to incorporate measurements at time scales that reflect the length of time protection needed.

(i) Lethal Dose (LD), Lethal Concentration (LC), and Lethal Time (LT) values – LD, LC and LT are all ways to compare insecticidal activity of a particular treatment. Labor (i.e., resources, money and time) involved in conducting testing is as follows: LD > LC ≥ LT. On page 26 of the TSD, there is a discussion of active ingredients versus product testing. The only reason dose response or LT_{50} type of data has value with regards to product evaluation is to validate a molecule as an active ingredient. After that, the defining question is "does the formulated product perform as claimed on the product label?"

The toxicity parameter used to characterize arthropod susceptibility depends on the nature of the assay. If arthropods consume a bait product, then the amount consumed can be measured and the toxicity of the active ingredient can be characterized in terms of the Lethal Dose. If arthropods are exposed to the end use product or an active ingredient where the amount absorbed or consumed is unknown, then the activity of the end use product or active ingredient should be described in terms of its Lethal Concentration. If the assay involves estimation of the amount of time to an endpoint, then Lethal Time should be used as the parameter to characterize the activity of the end use product or active ingredient.

Charge Question 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?

Panel Response – Bridging implies that data generated for one species or use are applied, with some additional data or scientific rationale, to the registration of a product against either the same or a similar species or the same or similar use in the U.S. This is consistent with the use of representative species to evaluate efficacy for species groups/taxa.

Some consideration of the species or species complexes involved, as well as the nature of the experimental work, is required. Foreign species data can be very useful and relevant in case of certain groups of species such as cockroaches, mosquitoes, certain ant species, lice, ticks, fleas, bed bugs, and some wood boring insects. It depends on whether the foreign species are similar to the U.S. species and show similar behavior, similar sensitivity and live under similar environmental conditions. Efficacy data on foreign species can be useful if the data were collected using a protocol similar to EPA's, and could be strengthened with the weight of evidence of peer-reviewed publications. Such data should be considered on a case-by-case basis and should be justified by the applicant and be judged by the authority. In certain clear cases, such as mosquitoes and cockroaches, it may be included in the guidelines that data on certain species, under certain test conditions or guidance standards, are acceptable.

One would expect a good product to work under a variety of conditions. Successes will emphasize this. Failures to provide control are more difficult to interpret (mentioned as variable test results), but not the successes. The Panel recommended developing a table for comparisons based on differences in product formulation use, target species, and environment in order to assess the suitability of the foreign data. Such a table might lend some consistency to decisions about what data to accept or not, and avoid issues with inconsistent decision-making that can frustrate registrants. Some considerations include the following:

- A full set of data on the foreign arthropod species would be needed for comparison.
- Foreign data collected on the same species of interest would be most useful. Attention should then focus on differences among environments. If research is based on different species, both species and environmental differences would need to be considered.
- Bridging data would best be accomplished if, at some point, a side-by-side comparison between the two species could be made. This can be difficult to do with foreign species since importation of foreign insects may require permits, specialized rearing facilities, and quarantine facilities to prevent accidental introduction into the U.S. This may be cost prohibitive.
- Congeneric species are probably close enough. Differences in dose responses among species in the same genus are likely to occur, but the magnitude of the differences may or may not be trivial, and could depend on the outcome measured.
    - Example: Permethrin impregnated bed nets were evaluated against *Anopheles stephensi* and *A. gambiese* (Hodjati and Curtis, 1999). KT_{50} varied by 1 – 10 minutes between species, depending on temperature. However, 24 h mortality was 97 – 100%.
    - One Panel member indicated that foreign *Anopheles* are more robust against pesticide activity than U.S. species and would provide a conservative estimate of efficacy.
- Differences among species in the same family could be greater than predicted.
    - For example, 90% of stable fly larvae can survive a 10X dose of *Bacillus thuringiensis israelensis* that would only kill 50% of horn fly larvae.
- Standardized laboratory trials may produce similar results for separate species, but field results could vary due to differences in biology, feeding patterns, host preference, larval developmental sites or behavior.
- The differences in physiological responses of different species could be confounded with habitat or ecological differences, making predictions of what might happen with U.S. species difficult.
    - For example, determining the efficacy of larvicides against black flies and mosquitoes can be strongly influenced by ecological factors such as water turbidity. The more turbid the water, the less efficacious the larvicide is. Failure can result from local conditions rather than a characteristic of the species.

(b) For what use patterns or product types might use of foreign data be most appropriate?
Panel Response - The Panel suggested that the following scenarios may be appropriate, if considering the use of foreign data:

- Screening data to establish efficacy or lethal dose against cosmopolitan pests such as cockroaches, mosquitoes, certain ant species, lice, ticks fleas, bed bugs and perhaps some wood boring insects.
- Simulated field studies or applications that involve artificial habitats, such as human habitations, where building materials and indoor environment can be reasonably controlled or characterized. There is a great deal of worldwide homogenization of species, especially those in the near environment of humans, due to global commerce and human and pet animal movement and transportation of goods.

- Field data with application of repellants on humans, although the attacking species complexes (mosquitoes and black flies, for example) should be characterized.
- Caution should be exercised before accepting efficacy data from foreign sources where the conditions, environment, materials applied, or species/species complexes are very different from those found in the U.S.
- The U.S. is a large country, and national registration requires field trials in five different geographic regions to be representative. Man-made borders are really artificial in terms of pest ecology. Using foreign field data might be useful to support the representativeness of the U.S. data, but should not replace it.
- It might be possible that bridging of foreign data could be useful for a significant quarantine pest such as cattle ticks (*Rhipicephalus* spp) or primary screwworm (*Cochliomyia hominivorax*).
- For invasive species, foreign data could be useful to speed up emergency registrations.
- Ethical considerations concerning human testing and animal testing have arisen, and in publishing, it is insisted upon that ethical standards be met; the same should be done with foreign data.
- Foreign data can be useful if a U.S. company, its subsidiary or U.S. product was involved in efficacy testing against the same species or a species similar to the one present in the U.S.

(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.?

Panel Response - The Panel believed that data generated outside of the U.S. could certainly be used to support U.S. products if it can be demonstrated that the conditions of the foreign trial are applicable to the U.S. situation and that the formulations, etc. used outside the U.S. will be similar to those proposed for use in the U.S. Efficacy data from outside the U.S. could be useful in case there is a special local need for registering a product for an invasive species that is becoming a problem in the U.S. or for an experimental use of a product for which data is not available.

(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?

Panel Response - Published data can be very useful, especially if it adds a new geographic domain to the data at hand. In one instance, published data was used to extend the registration of permethrin on cattle to include mosquitoes. The product was already registered for application to cattle against horn flies and published literature was used to extend its registration to include mosquitoes. Data available in peer-reviewed or credible scientific literature that originated from reputable laboratories can be useful in supporting product specific performance claims if the efficacy protocol is similar to that used by EPA. Such data can be useful to EPA in developing U.S. protocols should one not exist. The publication should contain the original data, not just summaries. Furthermore, the information on the formulation of the product and not just the active ingredient should be clear. A justification and summary of the new application would be

needed. Finally, it should also be kept in mind that there is a bias towards publishing only positive results, not negative results.

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

Panel Response - The Panel believed that if other sources of data can be fully reviewed and verified, then they should be considered. A personal communication or testimonial has limited value, unless it comes from experienced individuals. The practical experience of a group or organization of experienced and certified pest controllers in the field may provide additional information that can be used to support a field efficacy claim. Again, if the protocol for data generation is similar or better than that typically used by EPA, it may be acceptable especially if harmonization of efficacy protocols is feasible for U.S. products.

Charge Question 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?

Panel Response: In general, the Panel believed that many of the definitions are incomplete, not up to date and should, therefore, be reviewed and revised accordingly so that they reflect current scientific and industry thinking. Many of the EPA definitions are not clear, but by using EU comparable definitions when appropriate, a better quality text could be produced. Therefore, EPA should consider a review of all technical terms in the guidance documents. Efforts should be made to harmonize/standardize product performance data definitions with agreed upon laboratory and field research standards used by other organizations such as ASPCRO, Health-Canada, the EU and the Australian Pesticide and Veterinary Medicines Authority. A point of reference for all definitions should be provided and they all should be included in the general guideline 810.3000.

EPA's list of definitions is provided with these meeting minutes as Attachment 3. Those terms in Attachment 3 that were added or changed by the Panel for EPA's consideration are shown in shaded text. In addition, for EPA's consideration, the Panel made the following observations and suggestions during its review of all definitions/technical terms in the guidance document.

Control - The definition for "performance standard" in Appendix 3 contains the word "control." Certain products are designed for "kill" only and the Panel suggested that EPA provide additional clarity on how "kill" would fit within the performance standard that only contains the word "control."

Generally, there is no single standard definable as "commercially acceptable control" for reduction in numbers of pests or damage that is applicable to all pest management scenarios. The pest management objective or the specific level of reduction in pest numbers or damage that is required to support a "control" claim depends on factors such as the type of damage caused by the pest, economic threshold levels for the particular pests, the tolerance for damage or harm and the performance of other available commercial standard treatments. Where efficacy data show that a product, when used as directed, does not consistently reduce pest populations or damage to a level typically required to achieve commercially acceptable control, a lesser product label claim for "suppression" may be acceptable, provided that the applicant can show that the demonstrated level of performance has value in a pest management program.

The Panel suggested removing the word "suppress" from the definition of "control" and define "suppression" or "partial control" separately. In such cases, a product might not be as

efficacious as an available commercial standard treatment, but other performance characteristics of the product might contribute to its value as a pest management tool. A "suppression" claim might be considered in situations where, for example, a product has a new or different mode of action (i.e., chemistry) which, when incorporated into a pest management strategy that utilizes products with other modes of action, could contribute to management of pesticide resistance; or, the product has little or no negative impact on pest predators or parasites and, therefore, could be incorporated into an integrated pest management (IPM) program for management of a targeted pest and other pests.

Invertebrate public health pest - The definition of "invertebrate public health pest" should have additional clarification for "harm" and "life threatening situations". One could assume harm means that a pest can bite or sting, but to someone else, it might not be the case. "Life threatening situations" is a nebulous statement and it would be helpful to include examples of what EPA considers a life threatening situation.

Barrier treatment – It would be helpful to have a separate definition for barrier treatment. Not all barrier treatments would be covered by the definition of surface treatment. Some barriers provide repellency as an effect and do not necessarily kill. The definition provided by the EU seems to be the same or very close to the definition EPA is proposing.

Alien species versus exotic (invasive) species - In defining "alien species" or "exotic species", the Panel thought the date of introduction would be relevant.

Representative test species – EPA should consider adding the fact that representative test species can be reared in a laboratory and/or are available from an approved source.

Complete protection time (CPT) - Regarding the following phrase contained in EPA's definition of CPT, "…efficacy failure, as defined in the protocol used to conduct the study, " if the goal of EPA is to go to a universal labeling system (similar to sunscreens), then "efficacy failure" should be standardized in the definitions and guidelines so that there is no room for interpretation. Leaving it up to the registrant to define "efficacy failure" in a protocol will potentially lead to inconsistent data collection by EPA. The Panel suggested EPA define "efficacy failure" and that any changes made to guideline 810.3700 are based on the recommendations made by this SAP and reflected in updated definitions.

Percent repellency (% repellency) - The definition of percent repellency contains the following phrase: ".....from a surface treated with a pesticide....." The Federal Insecticide, Fungicide and Rodenticide Act provides a broad definition of "pesticide" and it includes "repelling" or repellents. This makes EPA's definition of percent repellency technically accurate; however, it creates confusion when looking at how repellency is defined in guidelines or literature. Conventionally, people outside EPA would consider those chemicals that repel insects different from "pesticides" that kill or manage a pest. Furthermore, most people outside EPA might not consider a repellent applied to the skin as a "surface treated with a pesticide". The Panel recommended clarification and differentiation between "pesticide" and "repellents." and redefining the definitions of repellency, percent repellency, etc. to reflect how repellents are actually used. Even though the definition of "pesticide" does cover repellents according to U.S.

law, the definitions should be clarified and refined to put repellents in a separate category. This is further confused by the inclusion of a "skin-applied repellent" definition. In general, there are many inconsistencies in the definitions and this will become even more important as EPA considers writing guidelines for evaluating spatial repellents and contact repellents or chemicals applied to clothing or fabrics.

Repellency - The definition of "repellency" contains the following phrase: "....driven away from a surface or space treated with a pesticide...." The Panel had similar comments as above. In this definition, EPA has included "space," implying spatial repellents. How is this different from the definition for spatial treatment? The distinction between personal spatial repellents and area repellents should be clearly made and EPA should revise its definition of repellency and perhaps by adding a clarified definition for "spatial repellency."

Spatial treatments - The words "controlling mosquitoes" are contained in this definition, but it may not be sufficient with the influx of spatial repellents (or treatments) to the marketplace, and in research and development. There are personal spatial repellents (e.g., clip-on devices), area spatial repellents and "spatial" or "space" treatments. The Panel was uncertain if area spatial repellents and spatial treatments should be treated the same under one definition. Is this definition intended to encompass those types of chemicals or devices? There is a difference in "controlling mosquitoes" and "repelling mosquitoes" from an area. How does EPA plan to account for these new products? For example, many of the mosquito coils use allethrin which has a knock-down effect. This does not necessarily equate to control as was discussed by the SAP in this meeting.

Colony Kill or Nest Kill - Additional clarification is suggested for these terms. What type of performance standard can be associated with a "colony kill" or "nest kill" claim for subterranean termites? These pests are typically reclusive, and only a portion of a colony may be visible at any given time (Kofoid, 1934). Even with genetic testing (Husseneder and Grace, 2001) of neighboring termite colonies, it is possible that a few individuals from a treated colony are able to survive having found an alternate possible food source. It is difficult to prove that a colony is completely destroyed, as opposed to simply suppressed to the point of not foraging at a treated site (structure or otherwise). The overall goal of any termite control method, including baits (Grace and Su, 2001) is structural protection. There seems to be little reason to allow product label claims that are difficult to substantiate when good information is available.

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

Panel Response - The Panel agreed that EPA should consider adopting the definitions provided by the EU in Appendix 4 of the TSD, because the EU definitions are clear to understand. Further, the Panel thought that all of the EU definitions were applicable and would be useful additions.

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

Panel Response - The Panel thought that EPA should consider additional or alternative definitions to describe product performance data and update them periodically as the science advances and as new health and environmental concerns are raised. Suggested additional or alternative definitions to be considered are as follows:

1. Consider adding definition for Lowest Effective Rate (LER) or Minimum Effective Dose (MED) as the minimum application rate required to provide effective control of a target pest, in terms of level, duration and consistency across a broad range of conditions in which the product will be applied. The LER will be specific to site/pest combination and management practices. LER is an important means of achieving sustainable pest management objectives, avoiding or delaying resistance development, and avoiding unintentional harm to workers, bystanders, or the environment.

2. Consider adding a definition for Suppression or Partial Control as a minimum of percent reduction in pest population adequate to alleviate public health or structural wood integrity concern.

3. Consider adding definitions for Personal Spatial Repellents, Area Repellents, Barrier Treatments, and Spatial Repellents.

4. Consider adding a definition for Morbidity Data of Product Performance if it can be shown that insects do not recover within 72 hours. Consider adding a definition for Moribund as the inability to move (crawl, fly or jump as appropriate) at 24, 48 or 72 hours after treatment.

5. Consider adding definition for "100% prevention of damage to wood" and "100% protection for five years from wood-destroying pests."

6. Consider adding definitions for Toxicology, Efficacy, Mode of Action, Pest, Monophyletic (tie into definition for "Genus"), Invertebrate, Exotic, Non-target Arthropod, Beneficial Arthropod, Arthropoda, Insecta, Arachnida and Chilopoda.

Charge Question 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.

Panel Response - The Panel provided comments on the lists of pests of significant public health importance as well as the list of wood-destroying insects for consideration under Charge Questions 1 and 2. An additional comment relates to pest species with supercolonies. Some pest species have a single-queen (monogynous) versus multiple-queen (polygynous) forms in the same species, as seen with fire ants or house infesting ants. House infesting ant species have monogynous colonies with a single nest or mound (monodomous) or polygynous supercolonies with multiple interconnected nests or mounds (polydomous), as seen with the imported fire ants. The polygynous, polydomous colonies of species pose a considerable challenge in meeting performance standards. For these, the performance standards need to be clearly established for monogynous, monodomous forms versus polygynous, polydomous forms. For example, the duration required to render colonies inactive over a certain area can be a performance requirement for polygynous, polydomous forms with supercolonies spread over a large area.

Regarding invasive species, many pest species were actually species introduced originally for agricultural purposes. The efficacy standard requirements for invasive species need to be developed as they become established. The USDA National Priorities List is a listing of known pest species that are intercepted at the ports of entry and if not contained, may threaten agricultural and urban landscapes. The list, with additional information on pest origin, biology and risk, can be accessed at the Cooperative Agricultural Pest Survey (CAPS) website: http://caps.ceris.purdue.edu/pest_lists. Species that threaten animal health may be found at http://www.aphis.usda.gov/animal_health/animal_diseases/. Emergency response to invasive pests requires a fast track pesticide registration process with easy access to any available source data on performance. Biological control alternatives for exotic pests and safeguards for their application should also be considered in an overall pest management strategy.

In terms of EPA's TSD, it was fairly informative; however, many suggestions from the Panel are provided in the responses to other charge questions throughout the meeting minutes. The presentations made by EPA personnel were enlightening and informative. It is important to clarify the scope of the document, especially with regard to whether or not livestock pests are included. It would seem appropriate to include them, since pests of pets are included. New guidelines for product performance could also include traps that contain semiochemicals as attractants. The EPA pest tables should be reviewed for consistency; however, in response to Charge Question 2, the Panel has provided suggested revisions to Tables I and II (see Appendix 1) that should be considered. One Panel member suggested leaving poultry in

Guideline 810.3200 as these are the source of many fly issues. Positive controls for repellents may neither be necessary nor should they always be used. Treatments are set by the objectives of a particular study. In the current protocols, there are a number of cases (TSD, Table 4) of unbalanced experimental designs. This should not be encouraged. Issues such as defining replicates, should be made clear for the various types of protocols, as well as the issue of pseudo-replication and confounding factors (e.g., pastures, habitats or treatments). This issue plagues researchers, and it is not always fully understood. Other particular comments made by the Panel about the TSD include the following:

Power analysis, Page 24: One Panel member was not certain of the need or the use for power analysis. Since many of the performance standards involve large differences, this Panel member believed it is safe to say that a statistical test that detects them is detecting a real difference. There have been many recent improvements in power analyses, but researchers are still not comfortable using them.

Sample size calculations: The Panel noted that sample size is usually determined by costs and time considerations associated with conducting a test.

Table 12, Page 25: The Panel re-emphasized that time frames should be specified.

Flow chart: In Unit X, it would have been useful to see a flow chart relating the different types of studies.

Good Laboratory Practice (GLP) protocols: There has been a great deal of objection to requirements for GLP protocols. Some effort should be made to understand why those in academia are resistant to them. Is it a real problem, a perceived problem, or is there reluctance due to a lack of training or otherwise? The idea of GLP and audited studies adds confidence to the integrity of the data. Further, GLP should conform to auditable performance standards.

Field studies: Performance standards for field studies need to be tailored to the types of damage that arthropods do, and the consequences of not preventing that damage. One Panel member proposed that for each guideline, a method of measuring the effectiveness of the end-use product should be suggested or required. For example, the USDA has developed a rating scale for evaluating the efficacy of toxic baits for fire ant control. For each guideline, it was suggested that EPA request input from 10-12 expert scientists. The draft guideline could then be reviewed by another group of scientists and the final draft guideline would then be made available for public comment. For repellent testing, rigorous laboratory testing with some field testing to validate laboratory results is very important. For insecticides, it was suggested that field testing using GLP standards is also very important.

Species identification: Correct identification of species through use of expert sources such as USDA identifiers, taxonomists at the universities, museums or extension services is needed.

Voucher specimens: There should be a provision to include voucher specimens for efficacy studies in order to confirm the identity of the pest being tested. Retaining voucher specimens at

repositories, collections or museums should be a component for establishing performance standards for a pest species.

EPA-industry cooperation: There is a need for updating product performance guidelines with reasonable agency-industry cooperation. Performance standards for imported fire ant (soil application), premise treatment, etc., do not exist. Performance standards should be clearly stated for all the test species. Wherever feasible, standards from EU and WHO should be considered, and in addition, "industry" may come up with achievable standards that EPA might consider.

Feasibility of performance standards: Proposed increase in product performance standards from 90% to 95-100% will create a burden for unobtainable results in many situations. There is an industry concern for conducting large scale field trials, or in general, any field trial using a 100% standard expectation, which is often unattainable. Minimum 90% performance under controlled laboratory conditions should be considered adequate. Registrants should be allowed to compete for achieving higher than required performance standards in proving the superiority of their products.

Testing active ingredient (AI) versus end-use product: Baseline standards using the active ingredient must be coupled with the testing of end-use product to meet the performance standards. The additives to an active ingredient in a product formulation (e.g., synergists, surfactants, emulsifiers and adjuvants such as wetting, sticking, spreading, extending, or fogging agents, etc.), may improve the delivery system of the end-use product.

Using indicator species for standardized efficacy tests: Selecting species as indicators for effectiveness for a whole taxon can be undesirable due to biological variability among species (morphology, structure, behavior, genetics, etc.). In addition, some species are limited in distribution and may be unavailable for testing. For the most effective product evaluation and practicality of testing, a readily available pest species with known tolerance to a product should be selected. This species will be representative of similar pest species with convergent behavioral characteristics. They may even belong to different genera in the same taxon. This approach may provide registrants flexibility of selecting pest species while still meeting the EPA data requirements.

Standardizing field trials for efficacy testing: GLP requirements for field trials should be broad enough to allow flexibility for each situation. Field conditions are influenced by weather, microenvironment, variability in pest populations, habitat condition and other factors. The flexibility required in test methods to address such situations can be accommodated in broad GLP requirements, and will reduce undue burden upon the registrant. Field trials should follow sound scientific principles and be incorporated into a well-designed protocol sufficient to meet the EPA data requirements.

Interiorscapes: Ornamentals and decorative live plant species that are treated with pesticides due to state quarantine regulations are of concern. Ornamental plants in indoor settings are in the same environment that humans live and work, and exposure to children, childbearing women and

pets can be of concern. There is a need for product label directions to educate end-users about treated ornamental plants destined to be used in interiorscapes.

Pesticides registered under 25(b): As discussed earlier, efficacy data is important for minimum risk pesticides in order to avoid false or misleading statements. There is an industry demand for applying the same or similar performance standards to 25(b) products as for any other registered products to prove their efficacy as reliable products.

Additional Comments Made by the Panel:

EPA asked the Panel's thoughts on *in vitro* surveys in place of any human studies. One Panel member felt that this may be the future for repellent studies and recommended that EPA should encourage the development of an *in vitro* bioassay system. However, *in vitro* systems lack the chemical and physical cues that, for example, mosquitoes use to find a host and to accept a host as suitable for blood feeding. Consequently, *in vitro* systems currently available would not be suitable for testing mosquito repellents. Another suggestion was that EPA should consider using semi-field studies with pathogen-free mosquitoes in large enclosures. This would allow for more natural conditions for test and evaluation, and lower health risks for the human subjects. One Panel member asked whether or not it was feasible to use animal models to settle the debate on landing rates versus biting rates when using human subjects. The response from another was that it is feasible is some cases (e.g., guinea pigs and ticks); however, it is equally difficult to get protocols approved to use laboratory animals. For example, one protocol to use quail to feed a *Culex* colony took 6 months for approval and often animals have to be tranquilized. This can create some logistical difficulties and concerns.

Finally, it was recommended that despite the discussions of *in vitro* studies and animal models, EPA should not abandon human subjects research for repellents. It is recognized that human subjects research is a sensitive issue and human subjects who volunteer must be protected. However, ultimately EPA is registering products to be used by humans on themselves, and the use is to protect them from arthropod bites and the potential transmission of disease. Therefore, they should be evaluated on humans which is analogous to the Food and Drug Administration (FDA) testing drugs. Most would not consider taking a drug that had not been through a Phase III clinical trial. The FDA requires human subjects testing for drug approval and/or diseases that are very serious. Therefore, the Agency should not abandon its recommendations for the use of human studies in efficacy testing of repellents.

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APPENDIX 1: TABLE 1 - Pests of Significant Public Health Importance

Class	Order	Family	Genus	Species	Motility Classification	Common Name	Range	Places/animals of Human Association	Pest Group	Pest Subgroup
Arachnida	Scorpiones	Buthidae	*Centruroides*	*sculpturatus*	Crawling	Arizona bark scorpion	Sonoran Desert, USA	Structures	3	
	Scorpiones	Buthidae	*Centruroides*	*vittatus*	Crawling	Striped bark scorpion	Mid-USA to nothern Mexica	Structures	3	
	Scorpiones	Buthidae	Centruroides spp.		Crawling	Bark scorpions	Southern USA too northern South America	Structures	3	
	Ixodida	Ixodidae spp.			Ectoparasite	Hard ticks	Worldwide	Human made and natural habitats	2	2a
	Ixodida	Ixodidae	*Rhipicephalus*	*(boophilus) spp.*	Ectoparasite	Cattle ticks	Tropical, subtropical with range expansion	Cattle, other livestock, and wildlife	2	2c
	Ixodida	Argasidae spp.			Ectoparasite	Soft ticks	Worldwide	Human managed and natural habitats	2	2b
	Acariformes	Pyroglyphidae	*Dermatophagoides*	*farinae*	Crawling	American house dust mite	Cosmopolitan	Structures		1a
	Acariformes	Pyroglyphidae	*Dermatophagoides*	*pteronyssinus*	Crawling	European house dust mite	Cosmopolitan	Structures		1a
	Sarcoptiformes	Psoroptidae	*Chorioptes*	*bovis (ovis var. bovis)*	Crawling	Cattle scabies	Worldwide	Domestic animals		1b
	Sarcoptiformes	Psoroptidae	Psoroptes spp.		Ectoparasite	Mange mites	Worldwide	Domestic and wild animals		1b
	Mesostigmata	Including at least 65 families			Ectoparasite	Mesostigmatid mites	Cosmopolitan	Human made and natural habitats		1c
	Mesostigmata	Dermanyssidae	Liponyssoides	sanguineus	Ectoparasite	Mouse mite	Worldwide	Rodents		1c
	Mesostigmata	Dermanyssidae	Dermanyssus	gallinae	Ectoparasite	Chicken mite (red mite)	Worldwide	Domestic fowls and wild birds		1c
	Mesostigmata	Dermanyssidae	Liponyssoides	sanguineus	Ectoparasite	Mouse mite	Cosmopolitan	Structures		1c
	Mesostigmata	Macronyssidae	*Ornithonyssus*	*sylviarum*	Crawling	Northern fowl mite	Temperate regions of the world	Domestic fowls and wild birds		1c
	Mesostigmata	Macronyssidae	*Ornithonyssus*	*bursa*	Crawling	Tropical fowl mite	Worldwide except a few islands	Domestic fowls and wild birds		1b
	Sarcoptiformes	Acaridae	All		Crawling	Stored product mites	Worldwide	Stored products		1b
	Sarcoptiformes	Sarcoptidae	*Sarcoptes*	*scabiei var. hominis*	Crawling	Human itch mite	Worldwide	Structures	3	1d
	Trombidiformes	Demodicidae	*Demodex*	*canis*	Crawling	Demodectic mange	Worldwide	Canines	3	1d
	Trombidiformes	Demodicidae	*Demodex*	*folliculorum* and *brevis*	Crawling	Eyelash mites	Worldwide	Structures	3	1d
	Trombidiformes	Demodicidae	*Demodex spp.*		Crawling		Worldwide	Domestic and wild animals	3	1d
	Sarcoptiformes	Acaridae	*Acarus*	*siro*	Crawling	Flour mite	Worldwide	Stored products		
	Sarcoptiformes	Acaridae	*Tyrophagus spp.*		Crawling	Mold mites	Worldwide	Stored products		
	Trombidiformes	Trombiculidae	Eutrombicula spp.		Crawling	Chiggers	Western hemisphere and Europe	Soil		1e
	Trombidiformes	Trombiculidae	Leptotrombidium spp.		Crawling	Chiggers	Asia and parts of Australia	Soil		1e
	Trombidiformes	Pyemotidae	*Pyemotes spp.*		Crawling	Itch mites	Worldwide	Human made and natural habitats		
	Araneae as specified									
	Araneae	Sicariidae	*Loxosceles*	*reclusa*	Crawling	Brown recluse spider	Southern Midwest to Gulf of Mexico, USA	Undisturbed areas around structures	4	
	Araneae	Sicariidae	Loxosceles spp.		Crawling	Fiddleback/violin spiders	USA and worldwide in warmer areas	Undisturbed areas around structures	4	
	Araneae	Theridiidae	Latrodectus spp.		Crawling	Cobweb incl. black widow spiders	Worldwide	Sparse vegitation habitats	4a	
	Araneae	Agelenidae	*Tegenaria*	*agrestis*	Crawling	Hobo spider	Western Europe, western USA, expanding range	Structures	4	
	Araneae	Clubionidae	Cheiracanthium spp.		Crawling	Sac spiders	Worldwide	Predators on plants, enter structures	4	
	Araneae	Clubionidae	Trachelas spp.		Crawling	Sac spiders	Worldwide	Predators on plants, enter structures	4	

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Chilopoda	Scolopendromorpha	Scolopendridae spp.			Crawling	Tropical centipedes	Worldwide	Wandering predators, enter structures	6	
Hexapoda	Phthiraptera	(Anoplura) Haematopinidae	Haematopinus spp.		Ectoparasite		Worldwide	Domestic and wild animals		6b
	Phthiraptera	(Anoplura) Linognathidae	Linognathus spp.		Ectoparasite		Worldwide	Domestic and wild animals		6b
	Phthiraptera	(Anoplura) Pediculidae	*Pediculus*	*humanus capitis*	Ectoparasite	Head louse	Worldwide	Humans		6a
	Phthiraptera	(Anoplura) Pediculidae	*Pediculus*	*humanus humanus*	Ectoparasite	Body louse	Worldwide	Humans		6a
	Phthiraptera	(Anoplura) Pthiridae	*Pthirus*	*pubis*	Ectoparasite	Crab louse	Worldwide	Humans		6a
	Phthiraptera	Menoponidae spp.			Ectoparasite	Chicken body louse	Worldwide	Poultry and wild birds	3	6c
	Phthiraptera	Boopidae spp.			Ectoparasite	Marsupial chewing louse	Australia	Wild animals	3	6c
	Phthiraptera	Gyropidae spp.			Ectoparasite		South America	Wild animals (Primates: Cebidae)	3	6c
	Phthiraptera	Trichodectidae spp.			Ectoparasite		Worldwide	Domestic and wild animals	3	6c
	Phthiraptera	Philopteridae spp.			Ectoparasite		Worldwide	Birds	3	6c
	Siphonaptera as specified				Ectoparasite					
	Siphonaptera	Pulicidae	*Echidnophaga*	*gallinacea*	Ectoparasite	Hen flea (Sticktight flea)	Worldwide	Poultry, wild birds and animals	7	
	Siphonaptera	Pulicidae	*Ctenocephalidea*	*felis*	Ectoparasite	Cat flea	Worldwide	Domestic animals	7	
	Siphonaptera	Pulicidae	*Ctenocephalidea*	*canis*	Ectoparasite	Dog flea	Worldwide and very common in Europe	Domestic animals	7	
	Siphonaptera	Pulicidae	*Pulex*	*irritans*	Ectoparasite	Human flea	Cosmopolitan	Humans, domestic and wild animals	7	
	Siphonaptera	Pulicidae	*Xenopsylla*	*cheopsis*	Ectoparasite	Oriental rat flea	Worldwide	Wild animals (Rodents)	7	
	Siphonaptera	Hectopsyllidae	*Tunga*	*penetrans*	Ectoparasite	Chigoe flea	Tropics and sub-tropics	Soil and sand	7	
	Blattodea	Blattellidae	*Blattella*	*germanica*	Crawling	German cockroach	Worldwide	Structures	8	
	Blattodea	Blattellidae	*Supella*	*longipalpa*	Crawling	Brownbanded cockroach	USA and Western Europe	Structures	8	
	Blattodea	Blattidae	*Blatta*	*orientalis*	Crawling	Oriental cockroach	USA, Northwest Europe, Israel, Australia, South America	Structures	8	
	Blattodea	Blattidae	*Periplaneta*	*australasiae*	Crawling	Australian cockroach	Worldwide in warmer climates	Structures	8	
	Blattodea	Blattidae	*Periplaneta*	*americana*	Crawling	American cockroach	Worldwide in warmer climates	Structures	8	
	Blattodea	Blattidae	*Periplaneta*	*fuliginosa*	Crawling	Smokybrown cockroach	Southern USA, Japan, and Tropics	Structures	8	
	Blattodea	Blattidae	*Periplaneta*	*brunnea*	Crawling	Brown cockroach	Africa and southern USA	Structures	8	
	Diptera	Ceratopogonidae	Culicoides spp.		Flying/aquatic	Punkies, biting midges, Granny Nippers	Worldwide	Human managed and natural habitats		12c
	Diptera	Ceratopogonidae	*Leptoconops*	*kereszi* complex	Flying/aquatic	Bodega black gnat	North America	Human managed and natural habitats		12c
	Diptera	Ceratopogonidae	*Leptoconops*	*torrens*	Flying/aquatic	Valley black gnat	Western USA	Human managed and natural habitats		12c
	Diptera	Culicidae	Culex spp.		Flying/aquatic	Culex mosquitoes	Worldwide	Human managed and natural habitats	11	
	Diptera	Culicidae	Culiseta spp.		Flying/aquatic	Culicseta mosquitoes	Worldwide	Human managed and natural habitats	11	
	Diptera	Culicidae	Aedes spp.		Flying/aquatic	Aedes mosquitoes	Worldwide	Human managed and natural habitats	11	
	Diptera	Culicidae	Ochlerotatus spp.		Flying/aquatic	Ochlerotatus mosquitoes	Worldwide	Human managed and natural habitats	11	
	Diptera	Culicidae	Anopheles spp.		Flying/aquatic	Anopheles mosquitoes	Worldwide	Human managed and natural habitats	11	
	Diptera	Culicidae	Psorophora spp.		Flying/aquatic	Psorophora mosquitoes	Worldwide	Human managed and natural habitats	11	
	Diptera	Culicidae	Coquillettidia spp.		Flying/aquatic	Coquillettidia mosquitoes	Afrotropical. Oriental, Australasian, North American and Palaearctic regions	Human managed and natural habitats	11	

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	Diptera	Simulidae	Simulium spp.		Flying/aquatic	Black flies	Worldwide	Human managed and natural habitats	12	12d
	Diptera	Simulidae	Prosimulium spp.		Flying/aquatic	Black flies	Worldwide	Human managed and natural habitats	12	12d
	Diptera	Psychodidae	Lutzomyia spp.		Flying	Phlebotomine sand flies	South America, Neotropics, and southern areas of Nearctic	Humans, domestic, and wild animals	12	12b
	Diptera	Psychodidae	Phlebotomus spp.		Flying	Sand flies	Africa, Asia, and Europe	Humans, domestic, and wild animals	12	12b
	Diptera	Psychodidae spp.			Flying	Moth and drain flies	Worldwide	Structures	12	10d
	Diptera	Tabanidae	Tabanus spp.		Flying	Horse flies	Worldwide	Human managed and natural habitats	12	12a
	Diptera	Tabanidae	Hybomitra spp.		Flying	Horse flies	Worldwide	Humans, horses, and cattle	12	12a
	Diptera	Tabanidae	Chrysops spp.		Flying	Deer flies, yellow flies, stouts	Worldwide	Humans, horses, and cattle	12	12a
	Diptera	Fanniidae	*Fannia*	*canicularis*	Flying	Lesser housefly, little housefly	Worldwide	Excrement	10	10b
	Diptera	Fanniidae	*Fannia*	*benjamini* complex	Flying	Canyon flies	North America?	Decomposing organic material		
	Diptera	Fanniidae	*Fannia*	*scalaris*	*Flying*	Latrine fly	*Worldwide*	Excrement	10	10b
	Diptera	Muscidae	*Musca*	*autumnalis*	Flying	Facefly	Europe, central Asia,India, Pakistan, China, North Africa, North America	Excrement (manure), cattle	10	10b
	Diptera	Muscidae	*Musca*	*domestica*	Flying	Housefly	Worldwide	Humans, domestic, and wild animals	10	10b
	Diptera	Muscidae	*Stomoxys*	*calcitrans*	Flying	Stablefly (a filth fly that bites)	Worldwide	Humans, domestic, and	12	10b
	Diptera	Muscidae	*Haematobia*	*irritans*	Flying	Hornfly (a filth fly that bites)	Europe and North America	Domestic animals	12	10b
	Diptera	Muscidae	*Hydrotaea*	*aenescens*	Flying		Warm regions of the Americas, Europe, Asia, and Australia	Cadavers and manure		10b
	Diptera	Muscidae	*Hydrotaea = Ophyra*	*leucostoma*	Flying	Black garbage fly	Nearctic?	Domestic poultry		10b
	Diptera	Calliphoridae	*Cochliomyia*	*hominivorax*	Flying	Primary screwworm	Caribbean, Central and South America	Domestic animals (fresh wounds)		9b
	Diptera	Calliphoridae	*Cochliomyia*	*macellaria*	Flying	Secondary screwworm	North America and American Tropics	Domestic animals (necrotic wounds)		9b
	Diptera	Calliphoridae	*Chrysomya*	*bezziana*	Flying	Old World screwworm	Tropical areas of the Old World	Domestic animals and humans		
	Diptera	Calliphoridae spp.			Flying	Blowflies	Worldwide	Humans, domestic, and wild animals		10a
	Diptera	Calliphoridae	*Pollenia*	*rudis*	Flying	Common cluserfly	North America and Europe	Structures		10a
	Diptera	Oestridae	Gasterophilus spp.			Bot (horse) flies	Worldwide	Humans, Domestic and wild animals		9c
	Diptera	Oestridae	*Gasterophilus*	*haemorrhoidalis*	Flying	Nose botfly	Worldwide	Equines and Reindeer		9c
	Diptera	Oestridae	*Gasterophilus*	*intestinalis*	Flying	Horse botfly	Worldwide	Equines		9c
	Diptera	Oestridae	*Gasterophilus*	*nasalis*	Flying	Throat botfly	Worldwide	Equines		9c
	Diptera	Oestridae	*Dermatobia*	*hominis*	Flying	Human botfly	Central and South America	Humans		9b
	Diptera	Oestridae	*Hypoderma spp.*		Flying/enteric	Warble flies	Worldwide	Domestic and wild animals		
	Diptera	Oestridae	*Oestrus*	*ovis*	Flying/enteric	Sheep botfly	Worldwide	Domestic and wild animals		
	Diptera	Drosophilidae	*Drosophila*	*repleta*	Flying	Fruit fly species (complex)	Worldwide	Decomposing organic material		
	Diptera	Drosophilidae	*Drosophila*	*melanogaster*	Flying	The Common fruit fly	Worldwide	Decomposing organic material		

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	Diptera	Hippoboscidae	*Melophagus*	*ovinus*	Flying/crawling	Sheep kedfly	Worldwide	Domestic sheep		9a
	Diptera	Sarcophagidae spp.			Flying	Fleshflies	Worldwide	Humans, domestic, and wild animals		10c
	Heteroptera	Cimicidae	Cimex spp.		Crawling	Human feeding bedbugs	Worldwide			
	Heteroptera	Cimicidae	*Cimex*	*lectularius*	Crawling	Common bedbug	Worldwide in temperate regions	Structures	13	13a
	Heteroptera	Cimicidae	*Cimex*	*hemipterus*	Crawling	Tropical bedbug	Worldwide in Tropics	Structures	13	13a
	Heteroptera	Reduviidae	*Reduvius*	*personatus*	Crawling	Masked hunter	Europe and North America	Structures and woodland	13	13b
	Heteroptera	Reduviidae	Triatoma spp.			Kissing bugs, conenose bugs		Structures, domestic and wild animals	13	13b
	Hymenoptera	Apoidae spp.			Flying	Bees (on a case by case basis)	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Andrenidae spp.			Flying	Mining bees	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Apidae spp.			Flying	Carpenter, bumble, digger, and honey bees	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Apidae	*Apis*	*mellipera*	Flying	European honeybee, hybrid Africanized bee	Worldwide (including the Americas and Africa)	Human managed and natural habitats	14	
	Hymenoptera	Apidae	Bombus spp.		Flying	Bumblebees	Worldwide	Human managed and	14	
	Hymenoptera	Colletidae spp.			Flying	Plaster bees or polyester	Worldwide	Human managed and	14	
	Hymenoptera	Halictidae spp.			Flying	Sweat bees	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Megachilidae spp.			Flying	Mason and leafcutter bees	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Crabronidae spp.			Flying	Cicada killer wasps	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Sphecidae spp.			Flying	Thread-waisted/digger/mud dauber wasps	Worldwide	Human managed and natural habitats	14	
	Hymenoptera	Formicidae	*Monomorium*	*pharaonis*	Crawling	Pharaoh ant	Worldwide	Human managed and natural habitats	15	
	Hymenoptera	Formicidae	*Linepithema*	*humile*	Crawling	Argentine ant	Established on six continents and maintaining invasive behaviors	Human managed and natural habitats	15	
	Hymenoptera	Formicidae	Pogonomyrmex spp.		Crawling	Harvester ants	Desert regions of North and South America	Natural habitats	15	15a
	Hymenoptera	Formicidae	Solenopsis spp.		Crawling	Fire ants	South America, Southern USA, Australia, Southeast Asia and Philippines	Natural habitats	15	15a
	Hymenoptera	Formicidae	*Myrmica*	*rubra*	Crawling	European fire ant	Europe, Asia, and North America	Natural habitats	15	15a
	Hymenoptera	Formicidae	*Tapinoma*	*sessile*	Crawling	Odorous house ant	Cosmopolitan	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	*Solenopsis*	*invicta*	Crawling	Red imported fire ant	South America, USA, Australia, southeast Asia	human managed and natural habitats		
	Hymenoptera	Formicidae	*Solenopsis*	*geminata*	Crawling	Tropical fire ant	Southern USA to coastal Peru	Human managed and natural habitats	15	
	Hymenoptera	Formicidae	*Solenopsis*	*molesta*	Crawling	Thief ant	Cosmopolitan	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	*Brachymyrmex*	*depilis*	Crawling		USA	Subterranean	15	
	Hymenoptera	Formicidae	*Brachymyrmex*	*patagonicus*	Crawling	Dark rover ant	Argentinia, Paraguay, Southeast USA and isolated urban areas of USA	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	Nylanderia spp.		Crawling		The Americas	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	*Nylanderia*	*fulva*	Crawling	Hairy crazy ant	South America and Southern USA	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	*Nylanderia*	*pubens*	Crawling	Caribbean crazy ant	Caribbean and Gulf coast of USA	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	Paratrechina spp.		Crawling	Yellow crazy ants?	Worldwide	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	*Tetramorium*	*caespitum*	Crawling	Pavement ant	Holactic	Structures/human managed habitats	15	
	Hymenoptera	Formicidae	Crematogaster spp.		Crawling		Worldwide	Structures/human managed habitats		
	Hymenoptera	Mutilidae spp.			Crawling	Velvet/cow killer/cow ants	Worldwide	Human managed and natural habitats	14	

APPENDIX 1: TABLE 1 - Pests of Significant Public Health Importance

	Hymenoptera	Pompilidae spp.			Flying	Spider wasps	Worldwide	natural habitats	14
	Hymenoptera	Vespidae	Vespula		Flying	Yellowjacket wasps	Worldwide	Human managed and natural habitats	14
	Hymenoptera	Vespidae	Dolichovespula spp.		Flying	Yellowjacket wasps	Various locations worldwide	Human managed and natural habitats	14
	Hymenoptera	Vespidae	*Vespa*	*crabo*	Flying	European hornet	Worldwide (endangered species)	Human managed and natural habitats	14
	Hymenoptera	Vespidae Eumeninae spp.			Flying	Potter and mason wasps	Worldwide	Human managed and natural habitats	14
	Hymenoptera	Vespidae Polistinae spp.			Flying	Paper wasps	Worldwide	Human managed and natural habitats	14
	Coleoptera	Dermestidae spp.			Flying/crawling	Carpet and stored product beetles	Cosmopolitan	Structures	
	Coleoptera	Curculionidae spp.			Crawling	Food product weevils	Worldwide		
	Lepidoptera	Pyralidae spp.			Flying/crawling	Food produst moths	Worldwide		
	Lepidoptera	At least10 Families spp.(*1)			Flying/crawling	Urticating caterpillars	Worldwide	Human managed and natural habitats	
Key									
Deletions =									
Doubtful entries =		(See charge question 2 narrative)							
Additions =									
	(*1) Families that have urticating caterpillars								
	Arctiidae								
	Lasiocampidae								
	Limacodidae								
	Lymantriidae								
	Megalopygidae								
	Noctuidae: Acronicta sp.								
	Notodontidae: Datana sp.								
	Nymphalidae								
	Saturniidae								
	Zygaenidae								

Appendix 1: Table 2 - Wood-Destroying Insects

Appendix 1: Table 2 - Wood-Destroying Insects

Class	Order	Infraorder	Family	Subfamily	Genus	Species	Wood type	Age of wood	Motility Classification	Common Name	Range	Place/animals of human association	Pest Group	Pest Subgroup
Hexapoda	Hymenoptera		Formicidae		Camponotus spp.				Crawling/flying	Carpenter ants	Worldwide	Structures, Human managed and natural habitats	16	
	Coleoptera		Oedmeridae		*Narcerdes*	*melanura*	Hard	Old	Crawling/semi-aquatic	Wharf borer	Temperate regions	Wet wood (usually maritime/aquatic)	17	
	Coleoptera		Cerambycidae		*Hylotrupes*	*bajulus*	Soft	New & Old	Crawling/flying	Old-house borer	Worldwide	Structures		
	Coleoptera		Cerambycidae spp.						Crawling/flying	Long-horned beetels	Worldwide	Human managed and natural habitats		
	Coloptera		Cerambycidae		*Anoplophora*	*glabripennis*			Crawling/flying	Asian long-horned beetle	Southeast Asia, present in North America, parts of Europe	Human managed and natural habitats		
	Coleoptera		Buprestidae		*Agrilus*	*planipennis*			Crawling/flying	Emerald ash borer	Asia, establishing in North America and Europe	Human managed and natural habitats		
	Coleoptera		Buprestidae spp.						Crawling/flying	Jewel or metallic wood-boring beetles	Worldwide	Human managed and natural habitats		
	Coleoptera		Curculionidae	Scolytinae spp.					Crawling/flying	Bark beetles	Worldwide	Human managed and natural habitats		
	Coleoptera		Anobiidae spp.				Soft	Old	Crawling/flying	Deathwatch beetles	Worldwide	Structures	17	
	Coleoptera		Bostrichidae spp.				Live and processed plants		Crawling/flying	False/horned powder-post beetles	Worldwide	Structures and man-made articles	17	
	Coleoptera		Bostrichidae	Lyctinae spp.			Hard	Old	Crawling/flying	True power-post beetles	Worldwide	Structures and man-made articles	17	
	Blattodea	Isoptera	Rhinotermitidae		Reticulitermes spp.				Crawling/swarming	Subterranean termite	Worldwide	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Rhinotermitidae		Heterotermes spp.				Crawling/swarming	Subterranean termite	Worldwide	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Rhinotermitidae		*Coptotermes*	*formosanus*			Crawling/swarming	Formosan subterranean termite	USA incl. Hawaii, southeast Asia, South Africa	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Rhinotermitidae		Coptotermes spp.				Crawling/swarming	Subterranean termites	USA incl. Hawaii, southeast Asia, South Africa	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Rhinotermitidae		*Prorhinotermes*	*simplex*			Crawling/swarming	Cuban subterranean termite	Florida, western Cuba, Jamaica, Puerto Rica	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Rhinotermitidae		Prorhinotermes spp.				Crawling/swarming	Subterranean termite	Florida, Caribbean, Australia, tropical islands, China	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Kalotermitidae		Kalotermes spp.				Crawling/swarming	Drywood termites	North America, Europe, Australia	Structures, Human managed and natural habitats	18	18b
	Blattodea	Isoptera	Kalotermitidae	Incisitermitinae	Incisitermes spp.				Crawling/swarming	Drywood termites	North America and Gulf of Mexico	Structures, Human managed and natural habitats	18	18b
	Blattodea	Isoptera	Kalotermitidae		Marginitermes spp.				Crawling/swarming	Drywood termites	North America, Australasian	Structures, Human managed and natural habitats	18	18a
	Blattodea	Isoptera	Kalotermitidae		Cryptotermes spp.				Crawling/swarming	Powder-post termites	Caribbean, Americas, Europe, Africa, China, Australasian	Structures, Human managed and natural habitats	18	18b
	Blattodea	Isoptera	Termitidae		Nasutitermes spp.				Crawling/swarming	Arboreal,subterranean/mound building termites	Australasian, Neotropical, Caribbean	Structures, Human managed and natural habitats	18	18c
	Blattodea	Isoptera	Termopsidae		Zootermopsis spp.				Crawling/swarming	Dampwood termites	North America	Structures, Human managed and natural habitats	18	18d

Key
Additions =
Live tree pests

APPENDIX 2

Alternative Performance Standards An Overview of US EPA and EU Standard Performance Levels		
Species	**Source**	**Performance Standard**
Mites	Appendix 5 page 69 TSD:	Dust mite: direct application: >95% mortality surface treatment: >75% mortality Scabies mite: direct application: 100% mortality CPT: >2h Dog follicle mite: direct application: >95% mortality surface treatment: >95% mortality
	EPA 810.3300 (Table 6):	100% kill or repellency for humans 90% kill or repellency for pets CPT >2-3h
	EU TNsG PT18:	lab test: >90% kill in 24 h, simulated use test: >90% kill in 1 week. field test: >90% kill gassing: 100% kill
Chiggers	EPA 810.3700 (Table 10):	CPT >2h
Ticks	EPA 810.3200 (Table 5):	90% in 1 week and 75% in 1 month (livestock)
	EPA 810.3300 (Table 6):	100% kill or repellency for humans 90% kill for pets CPT >2-3h
	EPA 810.3700 (Table 10):	>2h complete protection time
	EU TNsG PT18:	repellent >90% for claimed period, knockdown 100% + >80% kill in 24h Kill: >95% before feeding
	Comment: Because ticks are notorious vectors of human disease causing pathogens, repellents must be held to the high standard of at least 95% repellency. Acaricides should kill greater than or equal to 90% of the population when applied to backyards or other tick habitats. *EPA should recommend/require standard methods of pre and post-treatment surveillance so that effects of acaricide treatments could be measured.*	
Scorpions, Spiders, Centipedes	EPA 810.3500 (Table 8): EU TNsG PT18:	95% kill crawling insects: test cockroaches
Cockroaches	EPA 810.3500 (Table 8):	95% kill
	EU TNsG PT18: direct application: surface treatment: baits:	 lab: 100% kill in 1 h, residual 24 h >90% kill, field test >90% kill over 2-10 weeks. mortality >90%, field test >90% lab >95%, field test >90% kill

	IGRs:	lab >95%, field test >90% kill
Lice	EPA 810.3300 (Table 6):	100% kill or repellency CPT >2-3h
Fleas	EPA 810.3300 (Table 6):	100% kill or repellency for humans 90% kill or repellency for pets CPT >2-3h
	EU TNsG PT18: adults: larvae/ovae:	 100% knockdown + 90% mortality 48h > 80% inhibition of development
Keds, Bot flies, Screwworm, Filth flies, Biting flies	EPA 810.3200 (Table 5):	larvicide > 90%, adulticide 70-95% face fly adulticide: 20-60% kill in 2-3 days
	EPA 810.3400 (Table 7):	black fly larvae: > 80% kill biting midge larvae and adult >95% kill
	EU TNsG PT18: flies in general: surface/space treatment: larvicides: repellents:	knockdown >80%, mortality >90% in 24h mortality >90%, spatial: >80% skin: > 90%
	Comment: Screwworm may require higher level of performance as it is a quarantine issue and subject to eradication. Check with APHIS on this. Screwworm is a special case.	
Mosquitoes	EPA 810.3400 (Table 7):	95% mortality
	EPA 810.3700 (Table 10):	>2h complete protection time
	EU TNsG PT18: surface treatment: larvacides: repellents on skin: vaporizers, coils:	 knockdown>80% + >90 kill in 24h lab: 100% kill in 24 h (for slow products in 48-72h) (semi-)field tests: >90% kill of larvae and population reduction adults: >80% 100% for CPT claimed >80% for claimed period in field test
True bugs	EPA	no data found
	EU TNsG PT18:	knockdown: >90% after few min + >90 % kill in 1 hour 100% kill in lab, residual >95% for 24 hours. field test: >90% in 6-10 weeks
Bees, Wasps, Hornets	EPA	no data found
	EU TNsG PT18 (wasps only):	knockdown: >90% in 5-10 min, + >90% kill in 1 hour field test: 80% of nests(colonies) killed in 24h and 100% colony kill after 1-2 weeks
Ants (excl.	EPA	no data found

carpenter ants)	EU TNsG PT18:	knockdown: >90% in 5-10 min + >90% kill in 24 hours. lab test: 90-100% mortality in 24 h, field test: >90% kill after 2-8 wks claim for nest kill: 100% kill in lab, slow knockdown and 100% kill in field after 2-8 weeks baits: >95% kill in lab test and >90% kill in field after 2-4 weeks
Imported fire ants	EPA 810.3100 (Table 6)	control: >90% kill in 30-60 days suppression: >80% reduction for 60 days
	Comments: Individual colony application involve drenching ant mounds with emulsifiable concentrates or wettable powders diluted in water. In general, ant mounds should be drenched with one gallon of finished drench per 15 cm of mound diameter. The performance standard of 90% kill of the colonies treated should be applied with a minimum of 20 mounds treated in each of three separate test plots. Prior to treatment all active colonies in the test plot should be clearly identified. Complete kill of ants in the treated colony should be assessed at 24, 48 and 96 hours by disturbing the soil of the mound to determine if the mound contains living ants. At 36-48 hours after treatment, the area around the treated mound out to a distance of 10 meters should be searched for new colonies because the treatment may cause the ants to relocate their colonies into newly constructed mounds.	
Carpenter ants	EPA TSD Appendix 5 page 84:	>95% kill and repellency prevention of damage: >2 years structural protection: 100% for >5 years bait treatment: > 100% protection for > 3 years
	EU:	no data found
Wood-destroying beetles	EPA TSD Appendix 5 page 85:	>95% kill and repellency prevention of damage: >2 years structural protection: 100% for >5 years bait treatment: > 100% protection for > 3 years
	EU: EN 599-1:2009:	preventive treatment:100% kill or repellency
	EN 14128: 2004:	curative treatment: 80% kill after 8-24 weeks
Termites	EPA 810.3600 (Table 9):	soil applied: 100% control for 5 years impregnated wood: 100% for 2 years
	EPA 810.3800 (Table 11):	eliminate infestation in 12 months, Residual effect: another 12 months
	EPA TSD Appendix 5 page 87:	>95% kill and repellency prevention of damage: >2 years structural protection: 100% for >5 years bait treatment: > 100% protection for

		> 3 years
	EU: baits: barriers:	 no choice test: 100% kill in 48 hours-16 wks transfer test: 100% kill choice test: >95% kill fieldtest: 100% colony kill after 18 months 100% kill in lab test in field test: no soil penetration >10 mm, no perforation of film or access to other side of the barrier.

APPENDIX 3

EPA Definitions (including Public Health Claim)

EPA believes that definitions will be needed to assure a common understanding:

Note: Defintions that have been added to EPA's list or changed by the Panel are shown below in shaded text.

Alien species. Means, any particular ecosystem, a non-native species, including its seeds, eggs, spores, or other biological material capable of establishing a population and maintaining a presence over time.

Application Method. This is the method by which the product is intended to be applied. e. g. coarse spray, ultra-low volume (ULV) spray, bait station etc. The application method may also describe a specific pattern of treatment. This is particularly common for spray applications, but may also apply to other formulation types.

Application Rate. This is the rate at which the product will be applied in use, e.g. apply 100 ml of product per square meter, apply at a rate of 1 bait station per 3 m^2, spray for 20 seconds, etc. For efficacy assessment purposes, it is useful to consider the application rate as the amount of *active substance* applied to surface area or volume. Unlike a human health or environmental risk assessment which look at the maximum amounts of product which are considered to be acceptable (i.e. if the amount of active or application rate increase, the risks to man or the environment will be unacceptable), an efficacy evaluation looks at the *minimum* application/dose rate which will be effective (i.e. if the application rate decreases, the product may not work).

Bait treatments. The use products that are intended to be ingested by the target. This is normally through the insect feeding on the product directly, but may also include products which the target will come into contact with and later ingest during grooming/cleaning. The attractiveness of these products is through the use of a palatable food base, however they may also incorporate an attractant (e.g. a pheromone) which is intended to attract the target pests over a greater distance.

Complete protection time (CPT). Means the time from application of a repellent until efficacy failure, as defined in the protocol used to conduct the study.

Control. Means to provide residual kill of individuals of a species defined as a pest from a site or to suppress the ability of the species to reproduce so that the growth of the pest population is impaired for a specified duration following pesticide product application.

Contact (direct) spray treatments. These involve application directly onto insects, and are normally only possible when the insects are visible and available to be sprayed. In practice this often restricts direct application methods to controlling flying insects (such as adult moths

and houseflies), although some limited control of minor infestations of crawling insects (such as ants or beetles) may be possible.

Crack and crevice treatments. These are treatments where products are applied into cracks and crevices where insects hide and harborage, or through which they may enter the building. Such openings commonly occur at expansion joints, between different elements of construction and between equipment and floors. These openings may lead to voids such as hollow walls, equipment legs and bases, conduits and junction or switch boxes.

Direct application to pest. Means the product is applied directly to the pest organism itself. Pesticides in this category are often used to control flying insects (e.g. flies and wasps).

Disease causing pathogen. A single or multi-celled organism e.g. virus, bacteria, fungus, or nematode etc. when introduced into a host, causes illness/disease.

Fabric treatments. This encompasses two types of treatments. A fabric surface treatment means any application of a pesticide to cloth or clothing. This can include spray-on, or other treatments performed by the user before wearing the clothing or using the article, or treatments performed by a manufacturer. An impregnated fabric treatment means cloth or clothing that is treated by the manufacturer in a specific way such that the pesticide is bound to the fabric.

Formulation Type. This is determined by the product itself – e.g. a solvent based ready-for-use, a water based concentrate, a dusting powder, a gel bait, etc.

Frequency of treatment. Any specific interval between applications. Some products will be used in a way that will require more than one treatment. These products will give information on the treatment schedule which should be followed (e.g. insecticide re-treatment intervals or rodenticide re-baiting periods). Together, these pieces of information define the "normal use" of the product (e.g. a solvent based ready-for-use product to be applied as a coarse spray at a rate of 100 ml product m2), and efficacy must be demonstrated for the product when it is used in this way. Whilst information on the application method and rate etc. will normally be clearly defined, the claims made for the effects of the product are much more difficult to identify.

General label claim. Means a statement on the label of the pesticide product that the product is effective against a related group of invertebrate species, such as ticks, mosquitoes, or cockroaches.

Genus (plural genera). A taxonomic category ranked between species and family. It is an assemblage of closely related species; united by one or more derived features believed to be a single evolutionary origin/ancestor (monophyletic). It is the first name in a binomial or trinomial scientific name which is latinized, capitalized, and italicized. (Gullan & Cranston 2005; Triplehorn & Johnson 2005).

Group. Means a community of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species for the entire assemblage of taxa.

Invasive species. Means an alien species whose introduction does or is likely to cause economic or environmental harm or harm to human health.

Invertebrate control pesticide product. Means any pesticide product which is intended to destroy, repel, mitigate, prevent, or inhibit the establishment, reproduction, development or growth of any invertebrate species declared to be a pest.

Invertebrate public health pest. Means an invertebrate species which poses a health risk to humans, by transmitting disease causing pathogens, which cause harm, allergic reaction, and/or life threatening situations.

Introduction. Means the intentional or unintentional escape, release, dissemination, or placement of a species into an ecosystem as a result of human activity.

Kills. Means the mortality of the target pest as a result of feeding or contacting a pesticide.

Knockdown. Means that following the application of the insecticide, the insect is disabled, i.e., the insect is unable to maintain its normal functioning mode or there is a state of intoxication and partial paralysis which usually precedes death.

Polymorphic. A described species with two or more features/variants.

Percent control (% control) Means the numerical comparison of the pre- and post-treatment pest population counts when evaluated according to a recognized treatment program under actual field conditions.

Percent mortality (% mortality). Means the numerical comparison of the numbers of dead insects or other arthropods as determined by pre- and post-treatment counts or other measures correlated to population pressures against a vulnerable life stage(s) of the target pest.

Percent repellency (% repellency). Means the numerical comparison of the numbers of insects or other arthropods being driven away from a surface treated with a pesticide compared to an untreated surface, or being driven away from a three dimensional space treated with a pesticide compared to an untreated space.

Performance label claim. Means the effect of the product on a target pest as asserted on a pesticide label.

Performance standard. Means a benchmark or reference against which the ability of the pesticide product to control or repel an invertebrate pest species is compared.

Pest-specific label claim. Means a statement on a pesticide product label indicating that the product is effective against a particular invertebrate species such as German cockroach or black gnat.

Preventive/Remedial treatments for wood impregnation. Means dips, brush-on applications, sprays, or pressure treatments applied to susceptible wood materials. Treatments can be preventive (i.e., to provide structural protection before an infestation is present) or remedial (i.e., to kill and control an infestation when present).

Repellency. Refers to insects or other arthropods being driven away from a surface or space treated with a pesticide

Representative test species. Means a species whose response to a pesticide treatment is substantially similar to that of other members of the same taxa. For example, the German cockroach (*Blattella germanica*) and the American cockroach (*Periplaneta americana*) are the representative test species for all cockroaches for determining the efficacy of a pesticide product.

Skin-applied human repellent. Means a product intended to disrupt the host-seeking behavior of insects or other arthropods, driving or keeping them away from treated human skin. The repellent product, such as liquid, lotion, or spray, is intended to be applied directly to human skin.

Soil-applied termiticides. Means pesticide products that are applied to the soil beneath and adjacent to the structure, pre- or post-construction to kill or control termites. Treatments can be preventive (i.e., to provide structural protection before a termite infestation is present) or remedial (i.e., to kill and control a termite infestation when present).

Spatial treatments. These are treatments where the product is applied into the air rather than onto a surface. They are intended to disperse small droplets or particles into the atmosphere of a room or other open space, where they will normally stay for a period of time (very small particles may stay in the air for several hours under still conditions) (e.g., aerosol, fumigant applications, vaporizing strips, coils for controlling mosquitoes, ultra-low volume applications for public health pests (e.g., mosquito abatement), and misting systems.

Species. A group of interbreeding individuals producing fertile offspring (sharing a gene pool). Behavior and appearance are similar (polymorphic) and they share a common evolutionary history. (Gullan & Cranston 2005; Triplehorn & Johnson 2005).

Subgroup. Means a set of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species and part of a larger identified taxonomic grouping (e.g., Biting flies) that includes other pests species, which may or may not have a proposed pest group.

Spot treatments. These are treatments where products are applied to limited areas on which insect pests are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. These areas may occur on floors, walls and bases or undersides of equipment.

Surface treatments. These are treatments where the product is applied over surfaces such as walls, floors and ceilings, or as a treatment to outdoor surfaces. These treatments may

involve treating a large area of surface or may only involve application to a narrow band. Surface treatments can also include application to temporary or permanent bodies of water (e.g. in mosquito control) and to solid and semi-solid manure.

Structural protection. Means the elimination or prevention of termite or other wood-destroying pest activity in a structure as a result of a preventive or curative application of a pesticide product.

Taxon (plural taxa). A taxonomic unit or group of organisms classified together e.g. species, genus, family, order, phylum.

Wood-destroying applies to pests that feed on wood, and therefore are highly destructive to wood buildings or structures, and stored lumber. The impact on the structural integrity of buildings can represent significant economic or safety concerns given the costs of remediation.

Vector. Means any organism competent at transmitting a disease causing pathogen to humans and/or animals, including but not limited to mosquitoes, flies, fleas, cockroaches, ticks, or mites.

In refining EPA's list of definitions, the following references were consulted:

Gullan P. J., and P. S. Cranston. 2005. The Insects: An Outline of Entomology. 3rd edition Blackwell Publishing.

Triplehorn C. A., and N. F. Johnson. 2005. Borror and DeLong's Introduction to the Study of Insects. 7th edition. Thomson Brooks/Cole Publishing.