**PRE-PUBLICATION NOTICE**

On January 6, 2021, **Andrew R. Wheeler**, the EPA Administrator, signed the following document:

| | |
|---|---|
| Action: | Proposed Rule |
| Title: | Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests |
| FRL #: | 10011-06 |
| Docket ID #: | EPA-HQ-OPP-2020-0124 |

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (https://www.govinfo.gov/app/collection/fr) and on Regulations.gov (https://www.regulations.gov) in the docket identified above.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at http://www.regulations.gov.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

This page is intentionally blank.

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 158**

**[EPA-HQ-OPP-2020-0124; FRL-10011-06]**

**RIN 2070-AJ49**

# Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests

**AGENCY**: Environmental Protection Agency (EPA).

**ACTION**: Proposed Rule.

**SUMMARY**: The Environmental Protection Agency (EPA) is proposing to codify product performance data requirements to support registration of pesticidal products claiming efficacy against three categories of invertebrate pests: those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian longhorned beetle). The latter two categories are pests considered to be of significant economic or ecological importance. Product performance data (efficacy studies) document how well the pesticide performs the intended function, such as killing or repelling, against an invertebrate pest.

**DATES**: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***].

**ADDRESSES**: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0124, through the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets*.

**FOR FURTHER INFORMATION CONTACT**: Sara Kemme, Mission Support Division (7101M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347-8533; e-mail address: *kemme.sara@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this action apply to me?*

You potentially may be affected by this action if you are a producer or registrant of pesticide products making claims against the specified categories of invertebrate pests. The North American Industrial Classification System (NAICS) codes are provided to assist you and others in determining if this action might apply to certain entities. This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed could also be affected. Potentially affected entities may include, but are not limited to,

• Chemical Producers (NAICS 32532), e.g., pesticide manufacturers or formulators of

pesticide products, pesticide importers or any person or company who seeks to register a pesticide.

• Research and Development in the Physical, Engineering, and Life Sciences (NAICS code 541712), e.g., research and development laboratories or services that perform efficacy testing for invertebrate pests.

• Colleges, universities, and professional schools (NAICS code 611310), e.g., establishments of higher learning which are engaged in development and marketing of products for invertebrate pest control.

*B. What action is the Agency taking?*

EPA is proposing to codify product performance data requirements for pesticide products claiming efficacy against three categories of invertebrate pests: those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian longhorned beetle). The latter two categories are considered to be of significant economic and/or ecological importance.

Product performance data (efficacy studies) document how well the product performs the intended function, such as killing or repelling, against an invertebrate pest. The product performance data requirements being proposed would inform the data needed to substantiate pesticidal claim(s) made on the label of the pesticide products. The proposed numerical performance standards specify the level of efficacy that would need to be achieved for EPA to deem the submitted data as acceptable for a product bearing the specified claim(s) against the invertebrate pest. For the most part, the data requirements that EPA is proposing for codification are consistent with EPA’s current practices in data supporting applications for registration of a

pesticide product that bears a pesticidal claim against one or more of these pests.

This proposed rule presents the data requirements in tabular format. These tables link the efficacy claim on the label of a pesticide product with the data needed to substantiate that claim. EPA is proposing that the studies submitted by an applicant demonstrate the product's efficacy in studies using specified test species and with results demonstrating that the product achieved a specified level of performance, called a performance standard. Numerical performance standards, such as the percent mortality, percent repellency, percent knockdown, or complete protection time would need to be achieved to deem the data acceptable for the purpose of supporting a product making a claim against an invertebrate pest. The Agency believes that codifying essential elements relating to test species and performance standards will provide the regulated community a better understanding of the data EPA believes to be necessary to support registration of a product that claims efficacy against invertebrate pests.

EPA is proposing to:

• Codify a new subpart R in 40 CFR part 158 entitled, "Product Performance for Products Claiming Effectiveness Against Invertebrate Pests;"

• Rename 40 CFR part 158, subpart E to "Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins" in order to add specificity to the title and reduce the potential for confusion with the proposed subpart R; and

• Revise the data requirements for biochemicals in 40 CFR 158.2070 and microbials in 40 CFR 158.2160 to clarify the requirements for claims that would be subject to both subpart R and either subpart U or V.

Additionally, EPA proposes to update 40 CFR 158.1(c) to insert references to the

subparts to categorize them under the "scope of the subparts" section. EPA is also proposing to update subpart W at 40 CFR 158.2200(b) to insert a cross reference to the proposed subpart R to clarify the status of a product that bears both an antimicrobial claim and a non-antimicrobial claim against one of the pests specified in proposed subpart R.

*C. What is EPA's authority for taking this action?*

This action is issued under the authority of sections 3, 5, 10, 12, and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136-136y), as amended. Under FIFRA section 3(c)(2)(A), EPA is required to specify "the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time." EPA's codification of these data requirements is in 40 CFR part 158.

Additionally, the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) (7 U.S.C. 136 note, 133 Stat. 484) was enacted into law on March 8, 2019. PRIA was developed by a coalition of pesticide stakeholders representing seven different trade groups within the pesticide industry and public interest groups reflecting the environmental and farmworker safety communities. The result of this collaboration is that there are elements of PRIA 4 important to all the represented stakeholder entities in the coalition. PRIA 4 specifically establishes a new maintenance fee set-aside of up to $500,000/year to develop and finalize rulemaking and guidance for product performance data requirements for certain invertebrate pests of significant public health or economic importance. Specific to this rule, PRIA 4 requires EPA to finalize product performance data requirements by September 30, 2021. Specifically, the Act states that, "The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant public health or economic importance

specified in clauses (i) through (iv) of subparagraph (B) [bed bugs; premise (including crawling insects, flying insects, and baits), pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, or dips), and fire ants]."

This proposed rule includes product performance data requirements for the categories of invertebrate pests specified in PRIA 4 and, thus, is intended to satisfy the aforementioned rulemaking requirement. EPA notes that this proposed rule covers some invertebrate pests in addition to those specified in PRIA 4 due to their public health, economic, or ecological significance.

*D. Why is EPA taking this action?*

The following objectives were considered by EPA in developing this proposed rule:

1. *Obtaining reliable data to make the statutory finding.* The data submitted to EPA for review and evaluation as a result of this rule, once final, are expected to improve the Agency's understanding of the effectiveness of pesticides that make claims against pests of public health or significant economic importance.

2. *Provide clear and transparent data requirements*. Once final, the regulatory text proposed in this rule is intended to identify the specific data requirements that apply to pesticides making claims against certain categories of invertebrate pests. As with the original design of part 158 in 1984, and continued in 2007, given the variations in pesticide chemistry, exposure, and hazard, this proposal for product performance data requirements is intended to be clear and transparent while retaining sufficient flexibility to account for special circumstances.

*E. What are the estimated incremental impacts?*

In conjunction with this proposed rulemaking, EPA prepared an economic analysis entitled, "Cost Analysis of the Proposed Product Performance Rule" (Ref. 1) which presents an

analysis of the effects of codifying data requirements for product performance, as well as the effects of changes to label claim data requirements published simultaneously.

As noted previously, FIFRA mandates the Agency to register pesticides, including those used against invertebrate pests of public health importance, invertebrate wood destroying pests, and invasive invertebrate pests, under conditions of use such that the pesticide is of a composition to warrant the proposed claims. To make this finding, the Agency requires that registrants submit data demonstrating product efficacy against invertebrate pests of public health importance, invertebrate wood destroying pests, and invasive invertebrate pests. The product performance data requirements historically sought by the EPA and those being proposed in the rule are for claims against pests that either pose a threat to human health (e.g., mosquitoes and cockroaches) or have significant economic impacts, against which the efficacy of a pesticide cannot be readily determined by the user (e.g., termites and emerald ash borers). In those situations, market forces may operate too slowly to remove ineffective products. The proposal, once final, would codify data requirements for support of label claims that have, to date, been necessary, as determined on a case-by-case basis, to conduct assessments of product performance. This will provide needed clarity to firms seeking to develop and market products to control invertebrate pests of public health importance, invertebrate wood destroying pests, and invertebrate invasive pests.

This rule, when finalized, will clarify data requirements and therefore improve efficiency and effective use of resources by both the Agency and industry. Moreover, this rule-making measure will serve the public by ensuring that appropriate efficacy data are available to substantiate public health pest claims. While experience over time has led to a fairly standardized set of data requirements for invertebrate pests of significant public health importance, wood-

destroying insects, and invasive pests, codifying these data needs will ensure that new entrants to the field are clear about the information necessary to support registration. As a result, this rule, when finalized, would help alleviate uncertainties in the regulatory process and enhance transparency for stakeholders. The Agency is specifying data requirements for invertebrate pests of significant public health importance, wood-destroying insects, and invasive invertebrate pests to better indicate when certain data are needed or not. Consistent with 40 CFR 158.45 and proposed 40 CFR 158.1707, on a case-by-case basis the Agency may consider alternative data that are more appropriate than the proposed requirements considering the intended purpose and pesticidal claims of a pesticidal product.

EPA estimates that the proposed rule would result in cost savings of one million dollars annually across all registrants seeking label claims against invertebrate pests of significant public health importance, wood-destroying insects, and invasive invertebrate pests, equivalent to about $17,000 in savings per data package submitted to the Agency (Table 1). The average savings per registrant is $5,500 annually, considering that registrants do not submit products for review every year. This impact is expected to remain consistent over the next ten years, with total cost savings to industry of $1 million annually using either a 3% or a 7% discount rate. Over ten years, this amounts to about $8.5 million in savings at a 3% discount rate or about $7 million in savings at a 7% discount rate. The most expansive estimate of registrant cost savings of the proposed rule, including all likely impacts of the publication of the rule and the impact of changes in data requirements published concurrently with the rule, is $1.7 million annually. The estimated worst case is a cost increase to registrants of $600,000 annually.

EPA’s registration program and efficacy review has substantial benefits for consumers. It ensures product efficacy and label consistency across products, increases consumer confidence in

product efficacy, and reduces consumer search costs for effective products. This may help reduce the incidence of vector-borne diseases and damage from wood-destroying and invasive pests. Clarity in data requirements would enhance the efficiency of the registration process and aid new products to market, providing consumers with more product choices.

**Table 1—Benefits and Costs of the Proposed Rule**

| **Expected Benefits of the Proposed Rule** | |
|---|---|
| Cost savings per data package submitted | • Average impact per submitted data package of $17,000 |
| Cost savings per registrant submitting data packages | • Average annual impact per registrant of $5,500 |
| Annualized Cost Savings | • $1 million at both 3% and 7% discount rates<br>• This projection assumes 60 data packages submitted annually to the Agency. |
| Qualitative Effects | • For registrants: Quicker label changes, lower discovery costs, lower barriers to innovation.<br>• For consumers: Ensuring product efficacy and label consistency; increased consumer confidence in product efficacy; reduced search costs for effective products; and reduction in damage from covered pests. |
| **Expected Costs of the Proposed Rule** | |
| No increased risk to human health or the environment is expected from publication of the proposed rule. No increased costs to registrants or consumers are expected from publication of the proposed rule. Expected direction of costs for the Agency from the proposed rule are unknown. | |
| **Other Impacts** | |
| Small Business Impacts | • No significant impact on a substantial number of small entities<br>• Affected NAICS codes contain up to 5,438 small entities.<br>No increased costs to small entities expected, and cost savings may be relatively larger for small firms who do not have experience with the registration process for invertebrate pests of public health importance, invertebrate wood destroying pests, and invertebrate invasive pests. |

*F. What should I consider as I prepare my comments for EPA?*

1. *Submitting Confidential Business Information (CBI)*. Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the

outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

**II. Statutory Framework**

As a general matter, no person may distribute or sell an unregistered pesticide in the U.S. (FIFRA section 3(a)). The process for obtaining a registration for a pesticide so that it may be distributed or sold begins with submission to EPA of an application with the necessary data to review the application request. Taking into account the information submitted, EPA must grant the requested registration, if it concludes, when considered with any restrictions imposed, that:

• Composition of the proposed pesticide is such as to warrant the proposed claims for it;

• Labeling for the proposed pesticide and other material required to be submitted comply with the requirements of FIFRA;

• The proposed pesticide will perform its intended function without unreasonable adverse effects on the environment; and

• When used in accordance with widespread and commonly recognized practice, the proposed pesticide will not generally cause unreasonable adverse effects on the environment.

FIFRA section 3(c)(5) further provides that EPA "may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy."

The proposed regulations identify the data requirements EPA believes are necessary to determine whether the proposed claims of efficacy are warranted, the opportunity for waiver is covered by 40 CFR 158.45 and proposed 40 CFR 158.1707.

EPA notes that "unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs, and benefits of the use of any pesticide …" as described in FIFRA section 2(bb). That definition was amended in 1998 as part of the Food Quality Protection Act, requiring EPA to consider "the risks and benefits of public health pesticide separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this Act, the administrator shall weigh any risks of the pesticide against the health risks such as the disease transmitted by the vector to be controlled by the pesticide." While this rule proposes to codify product performance data requirements for invertebrate pests of significant public health importance, (Ref. 2) this rule does not address classification of pesticides as "public health pesticides" as that term is defined in FIFRA section 3(nn). The data requirements proposed in this rule will be used to make appropriate determinations under the FIFRA "unreasonable adverse effects" standard.

To determine whether the proposed use of the pesticide will not cause unreasonable adverse effects, EPA generally considers the maximum proposed use of a new pesticide to estimate the maximum exposure potential, evaluates the hazard data on the pesticide, and compares the rates at which effects are found based on well conducted studies with the maximum exposure estimate. However, for pesticides intended for use against pests of public health or economic importance, EPA has for some time considered whether the pesticide may cause human health, environmental or economic harm if its use as proposed will not work as

intended or claimed. Data on the pesticide's performance under the conditions of use proposed are essential to make this determination.

*A. Registration*

Section 3 of FIFRA contains the requirements for granting and maintaining registration. FIFRA section 3(c)(2) provides EPA broad authority, before and after registration, to require scientific testing and submission of the resulting data to the Agency. Under this authority, EPA requires such testing and submission of data through rulemaking, see, 40 CFR part 158 or, for existing registrations, through issuance of a "data call-in." (See, FIFRA section 3(c)(2)(B)). EPA may also request further data if the data submitted fail to adequately address an issue necessary for making the requisite statutory findings. (See, 40 CFR 158.75). Consistent with the requirements EPA has imposed and the data that have been identified as needed to review applications for registration of pesticides of significant health or economic importance, an applicant for registration must furnish EPA with data on the pesticide, its composition, toxicity, potential human exposure, environmental properties and ecological effects, as well as its product performance (efficacy).

*B. Registration Review*

FIFRA section 3(g) mandates that the registrations of all pesticides are to be periodically reviewed. Periodic review is needed as changes in science, public policy, and pesticide use practices occur over time. The registration review program was implemented via a regulation promulgated on August 9, 2006 (71 FR 45719) (FRL-8080-4). Therefore, starting in 2006, registration review began to replace EPA's reregistration program as the mechanism for systematic review of existing pesticides. The registration review process begins by reviewing the available information in the possession of the Agency and then determining if and what data are

needed to assess the current risks of a particular pesticide. Thus, as with registration, the data needed and the scope and depth of the Agency's review for registration review continue to be tailored to the specific circumstances and use of the registered pesticide. Section 3(g)(2)(A) of FIFRA authorizes EPA to require generation and submission of additional data necessary for registration review pursuant to its authority under FIFRA section 3(c)(2)(B).

**III. Regulatory Framework**

The existing regulatory data requirements for product performance for pesticides are contained in 40 CFR part 158, subpart E, and for the most part the table in 40 CFR 158.400(d) is specific to vertebrates (e.g., birds, rodents, etc.); 40 CFR part 158 subpart W also contains pesticide data requirements for antimicrobials. However, subpart E does not specifically require submission of product performance data for those pesticide products claiming effectiveness against invertebrate pests (e.g., insects, spiders, etc.). Instead, the test note in 40 CFR 158.400(e)(1) contemplates requiring the submission of product performance data on a case-by-case basis, consistent with the general authority in 40 CFR 158.75 to require additional data as part of the registration process, if the information that is required and submitted for registration is not sufficient to make the requisite statutory findings. EPA has relied on these authorities for some years to obtain needed product performance data for conventional pesticides intended for use against certain invertebrate pests of public health or economic significance.

Although the updating of 40 CFR part 158 regulations began years ago, EPA made no changes to the product performance data requirements at 40 CFR part 158, subpart E, as they relate to the invertebrate pests covered in this action. (72 FR 60934, October 26, 2007) (FRL-8106-5). However, EPA did make some changes to the data requirements for biochemical and microbial pesticides by codifying product performance data requirements for biochemical and

microbial pesticides in 40 CFR 158.2070 and 158.2160, subparts U and V, respectively (72 FR 60934, October 26, 2007) (FRL-8106-5). That final rule adopted the requirement for applicants to submit product performance data to support registration of biochemical and microbial products claiming effectiveness against invertebrate species.

This rulemaking proposes to create a new subpart R for invertebrate product performance requirements to capture the updates to the product performance data requirements for pesticides, and to make conforming edits to subparts E, U, V, and W.

**IV. Background**

Since the early years of the registration program, EPA has waived the need for product performance data for many pesticides, consistent with the congressional authority in FIFRA section 3(c)(5), to waive such data and to not make the finding that a proposed pesticide's "composition is such as to warrant the proposed claims for it." (44 FR 27932, May 11, 1979) (FRL-2767-8). However, EPA did not codify its early intent not to waive product performance data for pesticides intended for use against certain invertebrate pests. Specifically, in May of 1979, EPA initially announced the need for product performance data for "[i]nvertebrate control products intended for use in or on humans (or in or on pets for control of pests which attack humans) to control pests such as fleas, mites, lice, ticks, biting flies, and mosquitoes" and for"[i]nvertebrate control products intended for use either in premises or in the environment to control pests of sanitary or public health significance such as mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches, fire ants, hornets, wasps, poisonous spiders, scorpions, centipedes, and bedbugs." (44 FR 27932, May 11, 1979) (FRL-2767-8). In contrast, in other subsequent rulemaking actions, EPA announced its intent to require product performance data only for products "where lack of control would clearly result in adverse health effects" (47 FR 40659,

September 15, 1982) (FRL-2138-1) or where "control cannot reasonably be observed by the user…" (47 FR 40659, 40661) because other pests were more of an aesthetic and nuisance problem rather than one of public health.

Ultimately, EPA's final part 158 rule announced that EPA had "decided to rescind the proposed efficacy data waiver with respect to vertebrate control agents intended for control of pests that directly or indirectly transmit disease to humans" and included a test note indicating that EPA waived product performance data "unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his/her product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration." (49 FR 42856, 42875, October 24, 1984) (FRL-2591-5); 40 CFR 158.400(e)(1). That provision remains largely unchanged today, although in the subsequent updates to the data requirements for microbial and biochemical pesticides, EPA made clear that the submission of efficacy data would be required if "the pesticide product bears a claim to control … invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans." (40 CFR 158.2160). Thus, existing EPA regulations for conventional pesticides continue to presume the waiver of product performance data for invertebrate pests unless EPA exercises its discretion to require on a case-by-case basis submission of the data to support claims against pests, including

pests of significant public health importance.

In 2002, EPA issued Pesticide Registration Notice (PRN) 2002-1 in compliance with the requirement in FIFRA section 28(d) to coordinate with United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA) in identifying pests of significant public health importance. The list of pests identified in that PRN was "derived in large part from review of the pesticide/pest combinations for which efficacy (product performance) data are generally required to be submitted and reviewed prior to registration." (Ref. 2). EPA is the process of updating this document and has recently made an updated draft available for public comment (Ref. 2).

*A. Why does product performance matter?*

The primary goal of this proposal is to assure that pesticide products claiming effectiveness against an invertebrate pest of significant public health or economic importance perform effectively. This action addresses both health concerns and economic consequences stemming from pesticide products that might not perform as claimed on the label. EPA acknowledges that use of the term arthropod would include all the pests identified in this document. However, product performance data for additional invertebrate species, such as (but not limited to) gastropods (snails and slugs) that serve as intermediate parasite hosts or invasive mussels of ecological concern could be needed in the future. To account for the potential for future data needs, EPA will use the terms invertebrates or invertebrate pests in reference to pests in all three categories (pests of significant public health importance, invasive species, and wood-destroying insects).

Consistent with the regulatory text in 40 CFR 158.400(e)(1) and as noted in PRN 2002-1 and PRN 96-7: Termiticide Labeling, (Ref. 3). EPA has regularly exercised its discretion to

require submission of product performance data for pesticides intended for use against invertebrate pests of significant public health importance and of product performance data on pesticides intended for use against invertebrate pests of significant economic importance. Since 1984, particularly for insect repellents, the awareness of the incidence and severity of mosquito- and tick-borne diseases in the U.S. has changed. Mosquitoes and ticks are not merely nuisance pests: The Centers for Disease Control and Prevention (CDC) has determined that a single bite can transmit sufficient infectious material, i.e., a sufficient amount of pathogen, to cause serious, and sometimes fatal, disease. (Ref. 4). This is true for both mosquito-borne diseases such as West Nile Virus, St. Louis Encephalitis, and the Zika virus, and tick-borne diseases such as Lyme Disease. (Refs. 5 and 6).

If a person can become ill because of a single insect bite, a person using an ineffective insect repellent may not have the opportunity to realize that the insect repellent did not work as expected and then correct the situation by purchasing another product. Given the nature of these and other mosquito- and tick-borne diseases, an ineffective insect repellent can have serious and sometimes fatal consequences to a person's health.

Consequences can also include both health and economic impacts. For example, the common bed bug (*Cimex lectularius*) has long been a pest, feeding on blood, causing itchy bites and generally irritating their human hosts. EPA, CDC, and the USDA all consider bed bugs a pest of significant public health importance. Bed bugs can cause a variety of negative physical health, mental health, and economic consequences. Effects can include:

• Allergic reactions to the bed bug bites, which can range from no reaction to a small bite mark to, in rare cases, anaphylaxis (severe, whole-body reaction).

• Secondary infections of the skin, such as impetigo, ecthyma, and lymphangitis.

• Mental health impacts on people living in infested homes. Reported effects include anxiety, insomnia and systemic reactions. (Refs. 7 and 8).

Bed bug infestations are also an economic burden on society. The economic losses from health care, lost wages, lost revenue and reduced productivity can be substantial. The cost of effectively eliminating bed bugs may be significantly more than the cost of eliminating other pests because bed bug control usually requires multiple visits by a licensed pest control operator and diligence on the part of those who are experiencing the infestation. Control in multi-family homes is much more difficult than in single family homes because bed bugs frequently travel between units, either by direct transport by humans or through voids in the walls. Thus, there are additional costs and complexities associated with coordinating and encouraging participation from multiple residents. Also, if the pesticide product claiming to treat bed bugs is not effective and families are forced into repeated (and expensive) cycles of re-treatment, then serious health and economic impacts can occur.

While wood-destroying insects/structural pests are not pests of significant public health importance, they are similar in that the consequences of ineffective treatments can be severe. Unfortunately, the effectiveness of a treatment to protect a wooden structure is not readily apparent to the applicator at the time of application or during the occupancy of the building or home. It is only after the damage becomes apparent that the extent of needed repairs is determined. There is a potential for significant financial loss to the property owner. Thus, demonstrating the efficacy of pesticides intended to control structural pests has a unique importance. Data on the level of economic damage caused by structural pests on an annual basis are difficult to obtain but several authors have attempted to quantify it. The economic costs of termite property damage, preventative treatments, and structural repairs can be quite severe, with

estimated cost at approximately $5 billion annually. (Refs. 9 and 10). While these estimates are indicative of the cost nationwide, the costs borne by an individual property owner can be significant in their own right, up to and including, loss of the structure.

*B. Labels*

1. *Label requirements*. Pesticide product labeling provides information to users on, among other things, the product's intended uses, and how to handle and apply the produEPA's labeling regulations are contained in 40 CFR part 156. EPA reviews pesticide labels to determine whether the labeling is consistent with EPA's regulations, and is accurate, clear and enforceable. The accuracy of the information on the labeling is of particular importance for products making a claim to kill or repel pests of significant public health importance and wood-destroying pests. Such pests, if uncontrolled, can transmit disease pathogens, thus posing a widely recognized and significant risk to human health, and can result in significant economic impacts.

Consumers purchase products that claim effectiveness against a pest of significant public health importance precisely to avoid the harm these pests can cause. Consumers have a reasonable expectation that the claims on the pesticide label have a scientific basis, i.e., are based on valid evidence, and are neither false nor misleading. Such claims should be expressed using wording or graphics that are easily understood and require little or no interpretation by the consumer. To ensure that labeling provides consumers with accurate information concerning how long and how well the product works, EPA reviews and evaluates product performance (efficacy) data. Once the data have been reviewed and evaluated, then the Agency works to ensure that the labeling use directions and labeling claims are clear and consistent with the results of the supporting product performance data.

EPA believes that having reliable information concerning the effectiveness of pesticide

products that claim effectiveness against invertebrate pests results in sound regulatory decisions and accurate information on the labeling. Accurate labeling claims provide consumers with information they need concerning the effectiveness of the pesticide.

2. *Label Review Manual*. Consistently, the Agency has in the Label Review Manual explained the historical need for product performance data for products intended for invertebrate control. The Label Review Manual has for some time summarized the Agency's current practice of requiring product performance data to support claims for pesticides intended for use in or on humans (or in or on pets for control of pests which attack humans such as fleas, ticks, mosquitoes, and biting flies) and in premises or in the environment to control pests of sanitary or significant public health importance such as termites, wasps, scorpions, poisonous spiders, fire ants, cockroaches, centipedes, and bedbugs. (Ref. 11).

*C. EPA's Harmonized Test Guidelines for Invertebrate Product Performance*

1. *Existing Guidelines*. EPA has established a unified library for test guidelines issued by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA) and FIFRA. This library of test guidelines represents an Agency effort that began in 1991 to harmonize the test guidelines within OCSPP, as well as to harmonize the OCSPP test guidelines with those of the Organization for Economic Cooperation and Development, which includes representation of countries, including the U.S., throughout the world. The process for developing and amending the test guidelines includes several opportunities for public participation and extensive involvement of the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP), the Science Advisory Board (SAB), and other expert scientific organizations. New or revised guidelines are typically presented to SAP for peer

review. The purpose for harmonizing these guidelines into a single set of OCSPP guidelines is to standardize testing procedures that should be performed to meet the Agency's data requirements under FIFRA and TSCA. EPA's Invertebrate Control Agents, Product Performance Guidelines are listed in Table 2.

The guidelines themselves do not impose requirements. Instead, they provide recognized methods for conducting acceptable tests, guidance on reporting data, and definitions of terms. Since these are guidance, pesticide registrants are not required to use these guidelines to fulfill data requirements. Applicants may instead seek to fulfill the data requirements by other appropriate means or by using a non-guideline protocol. The applicant may submit a protocol of his own devising for the Agency to review. EPA notes that there is a PRIA fee category for submitting a protocol for EPA to review.

The guidelines identify thresholds for determining whether a product is effective. Since these thresholds are in guidance (not codified requirements), they are considered recommendations and not mandatory. EPA also acknowledges that the older (1998) guidelines, in particular, generally lack adequate, up-to-date guidance on efficacy data development, test protocols, and representative test species.

EPA notes that the Product Performance Guideline 810.1000 entitled, "Overview, Definitions, and General Considerations," discusses that product performance data are needed for any product that "bears a claim to control pests that may pose a threat to human health." This is specifically stated to include:

Public health uses of invertebrate control agents including, but not limited to, agents intended to control the following: Mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches, fire ants, hornets, wasps, poisonous spiders, scorpions, biting midges, centipedes, bedbugs,

human lice, and dust mites. (Ref. 12).

**Table 2—EPA's Series 810, Group C – Invertebrate Control Agents, Product Performance Guidelines**

| OCSPP Guideline Number | Guideline Title (Date) |
|---|---|
| 810.3000 | General Considerations for Efficacy of Invertebrate Control Agents (1998) |
| 810.3100 | Soil Treatments for Imported Fire Ants (1998) |
| 810.3200 | Livestock, Poultry, Fur- and Wool-Bearing Animal Treatment (1998) |
| 810.3300 | Treatments to Control Pests of Humans and Pets (March 1998) |
| 810.3400 | Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments (1998) |
| 810.3500 | Premise Treatments (2019) |
| 810.3600 | Structural Treatments (1998) |
| 810.3700 | Insect Repellents to Be Applied to Human Skin (2010) |
| 810.3800 | Methods for Efficacy Testing of Termite Baits (2004) |
| 810.3900 | Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products (2017) |

*D. Guideline Modifications Needed for the Future*

Those guidelines from 2004 and before require revision to remove any stated performance standards. Until the revisions can be made, this rule would supersede any species requirements or performance standards stated, or implied, in the guidelines applicable to invertebrate pests. EPA intends that any inconsistency that may exist between the guidelines and this rule should be resolved in favor of the regulations, once those regulations are finalized.

## V. Selection of Pest Categories for Subpart R

EPA has selected three pest categories for this proposed rule: Pests of significant public health importance, wood-destroying insects, and invasive species. The rationale for selection of these three categories follows.

*A. Pests of Significant Public Health Importance.*

1. *Background.* As previously noted, in 2002, EPA issued Pesticide Registration Notice (PRN) 2002-1 (Ref. 2), which presented the "List of Pests of Significant Public Health Importance." This document is currently under revision within the Agency. The 2002 list was

derived in large part from review of the pesticide/pest combinations for which product performance data have been required on a case-by-case basis to be submitted and reviewed prior to registration. This list was developed cooperatively by the U.S. Department of Housing and Urban Development, USDA, and EPA, with input from some non-governmental entities. EPA's Office of Pesticide Programs coordinated the review by experts in public health and/or pesticide use patterns to compile this list.

As indicated in PRN 2002-1 (page 1), the criteria for inclusion on the list were defined "broadly, to include pests that pose a widely recognized risk to significant numbers of people."

The listing of invertebrate pests (pages 6-9) is specified by the taxonomic name, as not all members of a particular taxon may be considered a pest of significant public health importance. EPA takes this approach when only certain members of a taxonomic group may be of public health significance because labels usually do not identify specific individual species. However, even if the label did identify a specific species, most product users are not able to distinguish among the members of a taxonomic group (i.e., identifying one tick species from another).

The invertebrate species of significant public health importance identified in this proposed rule as requiring submission of product performance data are derived from the invertebrate pest list identified in PR Notice 2002-1. Differences that exist between the species identified in the PR Notice and this proposed rulemaking represent the evolution of our understanding of the testing required to support claims against pests of public health concern. These invertebrate pests pose a threat of injury, disease transmission and/or pathogen transfer, and allergen production. Table 3 provides the rationale for inclusion in this rule of an invertebrate pest as a pest of significant public health importance.

**Table 3—Pests of Significant Public Health Importance from PRN 2002-1**

| Invertebrate Pest | Rationale for Inclusion |
|---|---|

| **(Common Species Name)** | |
|---|---|
| Mites | Produces allergens<br>Triggers asthma<br>Scabies<br>Itching and skin irritation with risk of secondary infection |
| Chiggers | Itching and skin irritation with risk of secondary infection |
| Ticks | Rocky Mountain Spotted Fever<br>Lyme Disease<br>Ehrlichiosis |
| Scorpions | Venomous sting |
| Spiders | Venomous bite |
| Centipedes | Venomous bite |
| Lice | Skin irritation and rashes<br>Epidemic typhus<br>Trench fever |
| Fleas | Annoying bites, allergic reactions, and rash<br>Plague |
| Cockroaches | Allergies<br>Transmission of Salmonella<br>Fecal contamination<br>Hepatitis |
| Bot Flies | Infest host and live under the skin with risk of secondary infection |
| Filth Flies | Carry pathogens<br>Food-borne illness |
| Mosquitoes | West Nile Virus<br>Dengue Fever<br>Malaria<br>Encephalitis<br>Yellow Fever<br>Chikungunya Fever<br>Zika |
| Biting Flies | Painful or annoying bites with allergic reactions |
| Sand Flies | Leishmaniasis |
| Triatomine Bugs | Allergic reactions<br>Chagas disease |
| Bed Bugs | Bites and allergic reactions |
| Ants | Stings to painful stings;<br>May be accompanied by severe or life-threatening reactions |
| Bees | Painful stings that may cause life-threatening reactions |
| Wasps, Hornets, and Yellowjackets | Painful stings that may cause life-threatening reactions |

2. *Disease Pressures*. EPA's proposal to establish product performance data requirements

for pesticide products claiming to control invertebrate pests reflects the most up-to-date science and is responsive to the improved understanding of the diseases being transmitted by invertebrates and the prevalence of these diseases. Since 1984, additional vector borne diseases have emerged. Mosquitoes and ticks can no longer be considered as merely annoying insects.

West Nile Virus was first identified in the U.S. in New York in 1999. Since then, West Nile Virus spread throughout the country and cases have been reported in the 48 contiguous states. West Nile Virus is carried by common mosquitoes (primarily species of *Culex*, though *Aedes* and *Anopheles* can also carry the virus).

• Serious Symptoms in a Few People—Approximately one in 150 people infected with West Nile Virus will develop severe illness. The severe symptoms can include high fever, headache, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, vision loss, numbness and paralysis. These symptoms may last several weeks, and neurological effects may be permanent. This is referred to as neuroinvasive West Nile disease and may result in death.

• Milder Symptoms in Some People—Up to 20 percent of the people who become infected have symptoms such as fever, headache, and body aches, nausea, vomiting, and sometimes swollen lymph glands or a skin rash on the chest, stomach and back. Symptoms can last for as short as a few days, though even healthy people have become sick for several weeks. This is referred to as West Nile Fever.

• No Symptoms in Most People—Approximately 80 percent of people (about 4 out of 5) who are infected with West Nile Virus will not show any symptoms at all.

Today, experts believe West Nile Virus is established as a seasonal epidemic in North America that flares up in the summer and continues into the fall. Persons over 50 years of age

have the highest risk of severe disease. (Ref. 13).

The Zika virus spreads to people primarily through the bite of an infected Aedes species mosquito (*Ae. aegypti* and *Ae. albopictus*). Zika can be passed from a pregnant woman to her fetus, which can cause certain birth defects. There is no vaccine for Zika. In 2015 and 2016, large outbreaks of Zika virus occurred in the Americas, resulting in an increase in travel-associated cases in the U.S., including widespread transmission in Puerto Rico and the U.S. Virgin Islands, and limited local transmission in Florida and Texas. In 2018 and 2019, there were no reports of Zika virus transmission by mosquitoes in the continental U.S. (Ref. 14).

In the past 20-25 years, Lyme Disease has increased in geographical distribution and in number of cases. The disease is carried by blacklegged (deer) ticks (*Ixodes scapularis* and *Ixodes pacificus*). The number and distribution of Lyme Disease cases correlates with the number and distribution of white tail deer, among other animal hosts. (Ref. 15). Deer populations have risen steadily in the last two decades, especially in suburban areas. (Refs. 16 and 17).

The first sign of infection is usually a circular rash, occurring in approximately 70 to 80% of infected persons. It begins at the site of a tick bite after a delay of 3-30 days and may gradually expand over a period of several days. The center of the rash may clear as it enlarges, resulting in a bull's-eye appearance. Patients also experience symptoms of fatigue, chills, fever, headache, and muscle and joint aches, and swollen lymph nodes. In some cases, these may be the only symptoms of infection.

Untreated, the infection may spread to other parts of the body within a few days to weeks, producing an array of discrete symptoms. These include loss of muscle tone on one or both sides of the face (called facial or Bell's palsy), severe headaches and neck stiffness due to meningitis, shooting pains that may interfere with sleep, heart palpitations and dizziness due to changes in

heartbeat, and pain that moves from joint to joint. Many of these symptoms will resolve, even without treatment.

After several months, approximately 60 percent of patients with untreated infection will begin to have intermittent bouts of arthritis, with severe joint pain and swelling. Large joints are most often affected, particularly the knees. In addition, up to 5 percent of untreated patients may develop chronic neurological complaints months to years after infection. These include shooting pains, numbness or tingling in the hands or feet, and problems with concentration and short-term memory.

Most cases of Lyme Disease can be cured with antibiotics, especially if treatment is begun early in the course of illness. However, a small percentage of patients with Lyme disease have symptoms that last months to years after treatment with antibiotics. (Refs. 18 and 19).

Rocky Mountain Spotted Fever is the most severe tick-borne rickettsial illness in the U.S. This disease is caused by infection with the bacterial organism *Rickettsia rickettsii*; it is carried primarily by dog ticks (*Dermacentor variabilis*) and wood ticks (*Dermacentor andersoni*). The initial symptoms of Rocky Mountain Spotted Fever include fever, nausea, vomiting, muscle pain, lack of appetite, and severe headache. Later symptoms include rash, abdominal pain, joint pain, and diarrhea. Pain and fluid loss can be so severe that hospitalization may be required. (Refs. 20 and 21).

EPA believes that tick and mosquito repellents have roles in disease prevention. Today, there is renewed interest in methods of preventing transmission of these diseases. CDC and other public health authorities have determined that efficacious insect repellents have a primary role in a multi-barrier approach in protecting the public from insect or tick-borne diseases. CDC recommends several personal protective practices to prevent tick and mosquito bites: one of the

most prominent and consistent messages is to use an insect repellent containing an EPA-registered active ingredient. (Refs. 22 and 23).

2. *Bed Bugs*. The U.S. has experienced a resurgence in the population of bed bugs. Bed bugs can impact people's physical and mental health. Physical impacts can include mild and severe allergic reactions to the bites, and secondary infections of the skin. Reported mental effects include anxiety and insomnia. (Refs. 7 and 8).

Both the EPA and the CDC believe that an integrated pest management program that combines both chemical and non-chemical treatments is the most effective way to control bed bugs. Among the integrated pest management methods, use of an effective pesticide product, labeled for use against bed bugs, applied according to the label directions is often necessary to control the population of bed bugs. (Ref. 8).

3. *Other pests of significant public health importance*. Other invertebrate pests cause painful bites and stings, provoke allergic responses, and transmit serious diseases. As discussed in PRN 2002-1, "cockroaches are controlled to halt the spread of asthma, allergy, and food contamination" and lice are controlled to prevent the "occurrence of louse-borne diseases such as epidemic typhus, trench fever, and epidemic relapsing fever in the United States." (Ref. 2).

*B. Wood-destroying Insects*

As previously explained, structural pests differ from pests of significant public health importance because health of individuals is not imperiled. However, the effectiveness of the treatment is not readily apparent to the applicator at the time of application or during the occupancy of the building or home, and a potential for significant financial loss to the property owner exists. EPA has generally required submission of product performance data for wood-destroying insects for over 40 years. USDA registered pesticides prior to establishment of the

EPA and also required product performance data in support of wood-destroying insects. The Agency issued PRN 96-7, entitled "Termiticide Labeling," (October 1, 1996) (Ref. 3) to provide guidance on label statements and minimum levels of product performance for soil treatment use of termiticide products. According to the PRN:

> The Agency believes that registration of a [termiticide] product demonstrating less than five (5) years of efficacy for control of termites is generally not appropriate from a safety or efficacy standpoint, considering the costs of treatment and the potential damage that could occur. The Agency does not believe that the homeowner should be subjected to such costly protection as would occur with products that are only efficacious for one year. Such products could, quite possibly, pose unreasonable adverse effects to the environment and/or humans because of higher risks than longer-acting alternatives. The more frequent treatments required could result in greater exposure and risk, or lower benefits, because of being less effective if not retreated, or more expensive if retreated.
> . . .
> EPA has always required efficacy data to be submitted by registrants to demonstrate that termiticides perform their intended function as claimed. EPA has reviewed such data prior to registration to assure that the benefits of the use would outweigh the potential risks.

*C. Invasive Species*

On February 8, 1999, President Clinton signed The Executive Order 13112 (64 FR 6183) (February 8. 1999), which is intended to "…to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause…." The Executive Order directed each federal agency to use relevant programs and authorities to:

• Prevent the introduction of invasive species;

• Detect and respond rapidly to and control populations of such species in a cost-effective and environmentally sound manner;

• Monitor invasive species populations accurately and reliably;

• Provide for restoration of native species and habitat conditions in ecosystems that have been invaded;

• Conduct research on invasive species and develop technologies to prevent introduction and provide for environmentally sound control of invasive species; and

• Promote public education on invasive species and the means to address them.

Invertebrate invasive species can impose serious economic costs by causing or vectoring diseases against native species that have little or no natural defenses. For example, an invasive species of significant note is the emerald ash borer, a wood boring beetle that is native to Asia. The emerald ash borer kills ash trees. Its presence was reported in southeast Michigan and Windsor, Ontario in 2002. Since then it has spread to at least 35 states and five Canadian provinces. Infested areas are under quarantine and restrictions have been imposed on moving fire wood. EPA has registered several pesticide products for use against the emerald ash borer after reviewing submitted efficacy data. (Ref. 24)

Another invasive invertebrate species, the Asian longhorned beetle, is also native to Asia and was first discovered in New York in 1996. The Asian longhorned beetle kills maple trees and other hardwoods. (Ref. 25). A very serious situation/crisis exists in New England, and USDA has established an extensive eradication program. EPA has also registered several products for use against the Asian longhorned beetle.

Invertebrates such as the emerald ash borer and the Asian longhorned beetle kill trees over very large geographic areas, thus, having substantial ecological and economic impacts by destroying both urban cover and forests used for recreation purposes and timber stands. According to a 2011 analysis (Ref. 26) entitled, “Economic Impacts of Non-Native Forest Insects in the Continental United States,” the following five categories of expenditures and losses can be used to illustrate impacts on forests.

• Federal government expenditures (survey, research, regulation, management, and

outreach),

• Local government expenditures (tree removal, replacement, and treatment),

• Household expenditures (tree removal, replacement, and treatment),

• Residential property value losses, and

• Timber value losses to forest landowners.

Within the 2011 analysis were cost estimates using the five previously described categories of the damage caused by three types of invasive insects: borers, sap feeders, and foliage feeders. Since some of the economic categories overlap, the total sum of all economic categories would include some double counting. However, the total of the insect types can be summed without double counting, which means that it is appropriate to sum the columns, but not the rows. Table 4 shows that most of the costs are borne by local governments and households, and the total damage is several billion dollars.

**Table 4—Annualized Invasive Species Damages in the U.S. ($ millions)**

| | **Federal Government Expenditures** | **Local Government Expenditures** | **Household Expenditures** | **Residential Property Value Loss** | **Forest Landowner Timber Costs** |
|---|---|---|---|---|---|
| **Borers** | $92 | $1,700 | $760 | $830 | $130 |
| **Sap Feeder** | $14 | $170 | $130 | $260 | $4 |
| **Foliage Feeders** | $110 | $170 | $160 | $410 | $18 |
| **Total** | **$216** | **$2,040** | **$1,050** | **$1,500** | **$152** |

Pesticide products are an important tool for managing the spread of an invertebrate invasive species and the related significant economic impacts. The availability of pesticide products with proven performance against an invasive species is important to slowing the spread of the invasive species. When circumstances necessitate the submission or citation of reliable data to support claims for controlling invasive species, EPA has the authority to require such product performance data.

Due to the sudden appearance and often rapid spread of invasive species, EPA does not

presently propose to codify a comprehensive list of all the specific invasive species for which product performance data might be deemed necessary. At this time, EPA is specifically proposing to codify product performance data submission requirements for the emerald ash borer and the Asian longhorned beetle. The submission of product performance data to support claims for effectiveness against other invasive invertebrate pests will be considered on a case-by-case basis.

**VI. Development of Invertebrate Pest Groups and Subgroups**

EPA has identified pest groupings on the basis of the biology and life history characteristics of the pests identified as public health or wood destroying pests. (Ref. 28). The groupings are taxonomically based. “Pest groups” and “pest sub-groups” are designations simply intended to convey the fact that some pests groups are part of larger groups. Therefore, when practical, “pest sub-groups” have been identified to define a meaningful subset of the larger group.

EPA developed the pest groups and pest sub-groups with the intention that product performance testing performed on a particular species can adequately represent all members of the pest group (or pest sub-group). The Agency intends these pest groupings to decrease data submission burdens on applicants and data review burden on the Agency as well as increasing the consistency, reliability, and integrity of data submitted to EPA. In some cases, EPA is proposing pest-specific claims, in addition to group and sub-group claims.

To develop these groupings, EPA considered species sensitivity. In certain cases, one member of a pest grouping is known to be significantly harder to kill, control, or repel than other members of the grouping. If product performance testing is performed using the species that is harder to kill, control, or repel, then logically, it can be assumed that the results of this testing

can be extrapolated to other members of the grouping. Additional considerations included the availability of species in a laboratory setting, the occurrence of species over wide areas and/or those species most commonly associated with transmission of diseases to humans.

## VII. Introduction to Part 158, Subpart R

### *A. General*

EPA is proposing to codify product performance data requirements pertaining to registration of pesticide products claiming efficacy against certain invertebrate pests. The proposed data requirements are consistent with the Agency's current practices concerning the data needed to register a pesticide product that claims effectiveness against invertebrate pests.

The proposed data requirements are presented, as appropriate, in table formats, with the needed data specified according to the claim on the label, the species to be tested, and the performance standards to be met. Once final, the regulations will provide the regulated community and other interested parties a better understanding of the data required to support registration of a pesticide product making a claim against an invertebrate pest identified to be a public health concern (e.g., ticks, mosquitoes, cockroaches, etc.), a wood-destroying insect (e.g. termites), or an invasive invertebrate species (e.g. Asian longhorned beetle).

The Agency is proposing to title the new subpart R in part 158, "Product Performance for Products Claiming Effectiveness Against Invertebrate Pests." The existing product performance data requirements in subpart E will be renamed "Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins." Additionally, EPA is proposing conforming edits to subparts U, V, and W.

### *B. Contents of Proposed Subpart R*

1. *General requirements*. Proposed 40 CFR 158.1700 contains the general requirements that would be applicable to any pesticide product that is making a claim(s) against an invertebrate pest, and describes how to use the data tables in proposed subpart R. These general requirements describe when product performance data may be required, specifically for products that bear a claim against a pest of significant public health importance or a pest of economic significance. The required tests must be conducted using the end-use product to ensure that the product's claims are supported in the form in which the user will be using the product.

Additionally, proposed 40 CFR 158.1700 provides a set of instructions on how to determine the product performance data required to support the pesticide product use for which registration is sought. This includes referring to all parts of subpart R, identifying the claims intended to be made on the product labeling, reviewing and understanding the performance standards that must be met or exceeded for the identified claims against the target pests, and understanding all applicable test notes.

2. *Definitions*. In order to ensure consistent implementation of proposed subpart R, EPA is proposing definitions specific to the subpart. Proposed 40 CFR 158.1701 and 158.1703 contain the definitions pertaining to subpart R. In particular, proposed 40 CFR 158.1701 defines many of the terms that are needed to assure a common understanding of the requirements and performance standards being proposed for codification under subpart R.

During the 2013 SAP, EPA received public comments and feedback from the SAP on the proposed definitions in the Technical Support Document (TSD) provided to the SAP. (Ref. 28). In addition, the SAP recommended several additional definitions that should be considered under this proposed rulemaking. After considering the comments provided, and based on the data requirements being proposed in this rulemaking, the proposed definitions represent those that are

most essential for understanding the requirements and regulatory text of the proposed subpart R. For those definitions that the SAP and public commenters provided feedback on or that were recommended then, but not included in this proposal, EPA intends to consider the utility of those definitions and will consider incorporating them into future guidance and rulemakings. The SAP and public comments on definitions associated with product performance data requirements are available in the docket for the SAP [EPA-HQ-OPP-2012-0574]. EPA's response to those comments are discussed in this document and associated docket. Other definitions included in the TSD have since been adopted in testing guidelines.

Where applicable, EPA derived the proposed subpart R definitions from existing guidelines. The definition for *Complete protection time* is very similar to the one found in Guideline 810.3700. The proposed definition of *Skin-applied insect repellent* is taken from Guideline 810.3700. The proposed definitions for *Soil-applied termiticides*, and *Bait treatment* were derived from information in Guidelines 810.3600 and 810.3800. For example, the *Bait treatment* proposed definition is similar to *Termite bait* in Guideline 810.3800. The definition of *Vector* is very similar to that in FIFRA 2(oo).

In the TSD presented to the 2013 SAP, EPA explained a pesticide for use against invertebrates and meeting one of the following circumstances might be characterized as making a public health pest claim requiring submission of product performance data:

• 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). For example: A claim is made to repel mosquitoes and/or ticks. Both mosquitoes and ticks transmit disease to humans. Or, a claim is made to kill bed bugs. Bed bugs are injurious to humans.

• The pesticide product is used in public health programs for vector control or for other recognized health protection uses to prevent or mitigate threats to public health.

• The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health organism and there is no other functional purpose for the ingredient in the product.

• The pesticide product is similar in composition to a registered pesticide product that makes explicit public health claims for control of invertebrate organisms.

EPA still agrees that these circumstances, in principle, identify the kinds of pesticides for which product performance data may be necessary. However, EPA is not proposing to codify the term "public health pest claim" as a means of identifying when data are required. Such a term is not necessary given the proposed regulatory text includes sections that specify the invertebrate pests and invertebrate pest groups/subgroups that would be subject to the proposed product performance data requirements if the pesticide is intended for use against those pests. EPA requests comment on whether there is utility in codifying an overarching definition of a "public health pest claim" for the purposes of subpart R, and if so, whether the definition presented to the SAP is appropriate.

In the 2013 TSD EPA wrote that:

> *A **public health claim*** is asserted if one or more of the following apply:
> --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 man (or both man and animals). For example: A claim is made to repel mosquitoes and/or ticks. Both mosquitoes and ticks transmit disease to man. Or, a claim is made to kill bedbugs. Bedbugs are injurious to man.
> --The pesticide product is used in public health programs for vector control or for other recognized health protection uses to prevent or mitigate threats to public health.
> --The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health organism and there is no other functional purpose for the ingredient in the product.
> --The pesticide product is similar in composition to a registered pesticide product that makes explicit public health claims for control of invertebrate organisms. (Ref. 28)

EPA believes that the circumstances presented in the 2013 TSD, in principle, identify the kinds of pesticides for which product performance data may be necessary. EPA also notes that existing regulations at 40 CFR 158.2204 provides definitions for a "public health claim" and a "nonpublic health claim" as they pertain to antimicrobial pesticide claims. EPA is not proposing to make any modifications to that provision, and any definition for a "public health pest claim" added to subpart R would be applicable only within proposed subpart R.

3. *Application Categories*. In proposed 40 CFR 158.1703, EPA is proposing to define a set of application categories to assist in defining the data needed to support registration. This section would only define application categories to the extent the terms appear in the proposed regulatory text and EPA believes they require definition. For example, the terms "bait treatments" and "spatial repellents" are defined. This section does not provide a listing of all application categories that would be covered by the proposed subpart R data submission requirements.

Application categories describe how and/or where the product is intended to be applied or used. The proposed application categories were derived after consideration of current practices and review of the application sites included in the Harmonized Test Guidelines (810.3000 through 810.3900). Oftentimes, these application categories will be used on pesticide product labeling, and, therefore, may be identified as a product performance labeling claim within the data requirement tables. Similar to the definitions in 40 CFR 158.1701, EPA received SAP feedback on some of the application category definitions. (Ref. 29). The application categories proposed in 40 CFR 158.1703 represent EPA's responses to that feedback for the application categories as applicable. These application categories are referred to in the portions of the

proposed regulatory text for the wood-destroying invertebrate pests.

4. *Performance Standards*. In proposed 40 CFR 158.1704, EPA is proposing a set of performance standards that, in the absence of performance standards specified elsewhere in subpart R, will apply generally and must be met for data cited to be considered acceptable in support of a specific labeling claim on the product's labeling.

a. *Performance standards for skin-applied insect repellents*: EPA is proposing that for skin-applied insect repellent labeling claims, the performance standard must be greater than or equal to 2-hours complete protection time.

Complete protection time (CPT) is defined in Guideline 810.3700 as "the time from application of a repellent until efficacy failure as it is defined in each study—for example, the time from application until the first efficacy failure event confirmed within 30 minutes by a second similar event." CPT has been the existing practice for determining efficacy of skin-applied insect repellents since the guideline was finalized in 2010. EPA presented this concept, along with a proposed minimum protection time of 2-hours, to the SAP in the TSD, as a means of ensuring that a skin-applied repellency product protects for a minimum amount of time given the potential variability of product results across different people.

The Agency believes that establishing a minimum CPT for skin-applied repellency products should be required because of the large variability in protection times experienced by susceptible individuals in the population. The SAP agreed that this was a reasonable standard, stating that "[i]f CPT is to be used, a minimum CPT of 2 hours was suggested by the Panel as a minimal criterion for product registration… A repellent of shorter duration may not provide sufficient, useful protection in practical terms and will give consumers a false sense of protection." (Ref. 29).

Additionally, EPA is proposing regulatory text for skin-applied products that reinforces that any testing required under part 158 which involves any human subjects must comply with all applicable requirements under 40 CFR part 26. For example, 40 CFR part 26 requirements are pertinent to 40 CFR part 158 testing requirements if the testing involves intentional exposure of human subjects. Protocols for such testing must be submitted to EPA for review prior to study initiation. Those protocols determined by EPA to involve intentional exposure of human subjects also require review by EPA's Human Studies Review Board (HSRB)) prior to study initiation.

b. *Performance standards for products other than skin-applied insect repellents*. Unless otherwise specified in the proposed 40 CFR 158.1700 – 158.1786, EPA proposes that the performance standard for a product performance claim against a pest must be greater than or equal to 90 percent. For non-wearable spatial repellents, the proposed performance standard is greater than or equal to 75%.

In the TSD presented to the SAP, EPA was considering performance standards of 95% for all other pest claims, with the exception of mites, lice, carpenter ants, wood destroying beetles, and termites. The 95% performance standards were initially chosen because they represented widely accepted standards at the time. (Refs. 28, 29, 30 and 31). EPA proposed these standards as a way to "define the levels of product performance that would need to be met in order for the studies to support product registration and labeling," and that proposing a specified threshold level or performance standard would be the "best means to assure that the products used to control invertebrate species are effective under conditions of use." (Ref. 28).

In response to the proposal, both the SAP and public commenters believed that a 95% performance standard would create a burden for unattainable results and would be cost prohibitive in most situations, particularly for large scale field trials, or in general, any field trial

using a 100% standard expectation. They argued that a minimum 90% performance under controlled laboratory conditions would be adequate. (Refs. 28 and 29). While they made this recommendation, the SAP stated that in special cases, EPA should retain 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. Additionally, the SAP stated that registrants should be allowed to compete by achieving higher than required performance standards, proving the superiority of their products.

After considering the SAP and public comments, with the exception of pests such as human mites, carpenter ants, termites, and wood-destroying beetles, EPA is proposing performance standards of 90% or greater instead of 95%. EPA believes that this standard will enable acceptance of registrations for products that provide a satisfactory level of control. Human mites and lice will retain a 100% standard, while the wood-destroying pests will have a 95% or greater standard for prevention of damage to wood, except for non-structural wood preservative treatments, which will have a standard of 100%. The standards for human mites, lice, and wood-destroying pests will be discussed in more detail in other sections of this proposed rule.

5. *Test Guidelines*. In proposed 40 CFR 158.1705, EPA is codifying a reference to EPA's Harmonized Test Guidelines, which set forth a recommended approach to generate the data required for product performance testing.

6. *Data Requirement Modifications*. In proposed 40 CFR 158.1707, EPA is proposing to state that on a case-by-case basis, the data requirements identified in subpart R may need to be adjusted for novel technologies or because a product's unusual physical, chemical, or biological properties or atypical use patterns would make particular data requirements inappropriate, either

because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. EPA recommends that registrants of novel technologies contact the Agency prior to conducting product performance testing. It should be noted that EPA has historically taken the position that data requirements can be adjusted or waived on a case-by-case basis per the procedures described in 40 CFR 158.45. This provision is not intended to supersede or alter the provisions at 40 CFR 158.45, but rather to clarify that EPA is proposing that the data requirements, including the performance standards, in subpart R may also be adjusted using the procedures consistent with those in 40 CFR 158.45.

7. *Invasive Species Claims*. In proposed 40 CFR 158.1708, EPA is proposing that when an application for registration or amended registration requests to put a claim(s) on its pesticide product's labeling for effectiveness against an invasive invertebrate species, then on a case-by-case basis, EPA may require submission of product performance data to support those claims for effectiveness. Due to the sudden appearance and often rapid spread of invasive species, EPA does not presently intend to codify a comprehensive list of the specific invasive species for which product performance data might be deemed necessary. USDA maintains a list of invasive species profiles, which can be used as guidance. (Ref. 32). EPA is specifically proposing to codify product performance data submission requirements for the emerald ash borer and the Asian longhorned beetle. The submission of product performance data to support claims for effectiveness against other invasive invertebrate pests will be considered on a case-by-case basis.

EPA notes that the Agency currently has authority to require data submission on a case-by-case basis when necessary to evaluate a pesticide product (see 40 CFR 158.75). This provision is intended to clarify that whether or not a claim is against an invasive species is a factor in determining whether product performance data is necessary to evaluate a pesticide.

8. *Invertebrate Disease Vector Claims*. In proposed 40 CFR 158.1709, EPA is proposing that if a registrant requests a labeling claim specific to a disease vector, additional testing conducted with the species specific to that disease vector claim is required if that species is not already required under subpart R as part of the pest group tested. For example, if a product claims to repel Asian longhorned ticks that may carry Japanese spotted fever, caused by *Rickettsia japonica*, then the registrant must generate data using the species that is known to carry the disease indicated, the Asian longhorned tick in this case. This requirement will ensure that all disease vector claims are supported by appropriate product performance data demonstrating the required performance standard should an unknown public health threat emerge in the future.

9. *Structural and Wood-destroying Pest Claims*. In proposed 40 CFR 158.1710, EPA is proposing that if an application for registration or amended registration requests a labeling claim specific to a structural or wood-destroying pest that is not identified in 40 CFR 158.1782 through 158.1786, EPA may require submission of product performance data to support those claims for effectiveness. This requirement will ensure that any claim against structural and wood-destroying pests that have not been accounted for at this time are supported by product performance data in the event that a new threat emerges.

10. *Pest Specific Claims*. EPA is proposing to codify product performance data submission requirements for pest groups, sub-groups, and some specific species. EPA uses the term “Pest group labeling claim” to mean a claim or statement on the labeling of the pesticide product that the product is effective against a group 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. The term “Pest sub-group labeling

claim" means a claim or statement on the labeling of the pesticide product that the product is effective against 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 pest species, which may or may not have a proposed pest group. The term "Pest-specific labeling claim" means a claim or statement on the labeling of the pesticide product that the product is effective against a particular arthropod species, such as German cockroach or house fly.

In addition to the group and sub-group claims, EPA is proposing to codify requiring product performance data for a number of pest-specific claims. As previously noted, the representative test species were selected on the basis of vigor of the pest species and the likely ability of the species to serve as an adequate surrogate for other pests in the group, as well as other factors including their availability for laboratory testing, ubiquity, and whether they are one of the primary drivers of the human health concerns within a grouping. (Ref. 1). The 2013 TSD envisioned that in many cases "[i]f representative taxa are provided, species specific data may not be required, as the group and any/all individual species within the group can be supported by supporting the general claim." (Ref. 28).

For pests that are not listed as a "pest-specific claim" in proposed subpart R, EPA proposes that the data required to support a group claim would also be sufficient to support pest-specific claims for species within that group. For example, the pavement ant (*Tetramorium caespitum*) is not listed as a pest-specific claim in proposed subpart R because it is not a pest of significant public-health importance (nor is it a wood-destroying insect) and no pest-specific product performance data would need to be submitted to add a claim against pavement ants to a label. In contrast, cluster flies (*Pollenia rudis*) are listed as a pest-specific claim in this proposed

rule because of their significant public health importance. These pest-specific claims are consistent with EPA's current practices. Thus, consistent with the Agency's current practices, pest-specific data would need to be submitted to add a pest-specific claim against cluster flies to a label in addition to any data submitted to support the group claim against "filth flies." EPA also notes that the provisions at 40 CFR 158.75 and proposed 40 CFR 158.1708 would also permit the EPA to require pest-specific data on a case-by-case basis when necessary to evaluate a pesticide product. These provisions allow EPA to address the Agency's data needs in the face of emergent invertebrate pest concerns.

EPA requests comment on the pest-specific claims covered by this proposed rule and whether there should be additional pest-specific claims added to subpart R, or if some of the ones included in the rule are unnecessary.

*C. Data Requirements for Subpart R*

The data requirements that EPA is proposing for codification are consistent with the Agency's current practices when considering the product performance data needed to register a pesticide product that bears a pesticidal claim against one or more of these pests or pest groups/sub-groups. FIFRA section 3(c)(2) directs EPA to specify the kinds of data that applicants and registrants must submit to EPA to support regulatory determinations under FIFRA. The data requirements for pesticide products are codified in 40 CFR part 158. Product performance data (efficacy studies) document how well the product performs the intended function (such as killing or repelling) against an invertebrate pest. The product performance data needs being considered in this rule would link the labeling claim for pesticide products claiming efficacy against an invertebrate pest with the data needed to substantiate that claim. EPA views these standards as performance standards for the acceptability of data, and

thus EPA views them as waivable under 40 CFR 158.45.

1. *Mites (excluding Chiggers)*. In 40 CFR 158.1712, EPA is proposing the required test species and performance standards in order to make a labeling claim against dog follicle mites, dust mites, and the human itch or scabies mite. EPA is proposing to list chiggers, which are mites, in a separate section.

As indicated in the TSD presented to the SAP, dog follicle mite infestations are typically commensal in nature, but can cause demodectic mange in susceptible animals. This can pose a serious risk to stricken individuals, which typically have pre-existing immune system issues. For this reason, a 100% performance standard is being considered for these applications.

Dust mites pose no direct threat of injury, disease transmission, or discomfort. However, dust mites are included as a pest of significant public health importance because they produce allergens in their feces and cast exoskeleton that can result in asthma and allergic reactions. EPA believes that it is impractical to expect complete elimination of the dust mite population in a structure. The focus should be to reduce the agent of concern (i.e., the allergen) to acceptable levels. This can be achieved through a reduction in the target pest that is less than is generally necessary for a pest that acts directly against its host. EPA initially proposed a 75% performance standard to the SAP for surface and fabric treatments, and a 95% performance standard for direct application to dust mites. However, after considering the responses received through the SAP and public comment, EPA is proposing a 90% performance standard for dust mites to be consistent with the recommendations provided on the performance standards for other species testing.

During the SAP, one commenter indicated that for mites, the proposed performance standard of 100%, as considered by EPA, was too high. Instead the commenter advocated for

90%, while indicating that 95% would be achievable. (Ref. 33). The 90% standard is being proposed for some labeling claims for the dog follicle and dust mites, but for human itch or scabies mites, EPA disagrees with lowering the performance standard since scabies mites directly infect and are easily transferred among hosts. A human skin-applied topical repellent performance standard of ≥ 2-hour complete protection time is also being proposed.

EPA also notes that any testing conducted with human subjects must comply with all applicable requirements under 40 CFR part 26.

2. *Chiggers*. In the proposed 40 CFR 158.1714, EPA is proposing to require testing for labeling claims against chiggers. Chiggers are being proposed in the rulemaking due to their bites causing itching and skin irritation with the risk of a secondary infection. Additionally, EPA is proposing the performance standards established under 40 CFR 158.1704 to apply to testing for chiggers.

During the SAP, the Panel noted that *Trombicula alfreddugesi* (as presented in the TSD) is now renamed as *Eutrombicula cinnibars*. EPA was unable to verify this and has maintained *Trombicula alfreddugesi* as was presented in the TSD. EPA requests comment on whether this is correct, and if the name has changed, EPA requests a reference to the revised name.

3. *Ticks*. In the proposed 40 CFR 158.1718, EPA is proposing to require the test species and performance standards to labeling claims against ticks, cattle ticks, and soft ticks. EPA is proposing several tick species due to their potential to transmit diseases, such as Rocky Mountain Spotted Fever, Lyme disease, and ehrlichiosis. For performance standards, EPA is proposing standards consistent with 40 CFR 158.1704.

To make a claim against “ticks,” EPA is proposing to require a total of three hard tick species as representative of ticks in general. As presented in the TSD and based on

recommendations from the SAP, products claiming “ticks” must test for the blacklegged tick (*Ixodes scapularis*) and lone star tick (*Amblyomma americanum*), and a third species tested must be either the American dog tick (*Dermacentor variabilis*), the brown dog tick (*Rhipicephalus sanguineus*), or, as suggested by the SAP, the Rocky Mountain wood tick (*Dermacentor andersoni*). Because ticks are high stakes disease vectors and because consumers have difficulty differentiating between species, for a claim against any specific species of “ticks” all the representative species for the “ticks” claim must be tested. In addition, because these are pests of significant public health importance that the public strongly associates with the diseases they vector, EPA would also require submission of data on the specific pest claimed. EPA does not typically receive pest-specific claims for ticks other than those that are representative species for ticks. However, the Asian longhorn tick is an emergent pest in this category and EPA would require pest-specific data for a pest-specific claim against the Asian longhorn tick or any other pest specific tick claim. This would be in addition to testing on the representative species.

In addition to the required test species for a “tick” labeling claim, EPA is also proposing specific parameters regarding required species for “ticks” under certain testing circumstances. These specific parameters include:

i. For products intended to be applied to dogs, testing is required on three species: blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), and brown dog tick (*Rhipicephalus sanguineus*).

ii. For products intended to be applied to cats, testing is required on three species: blacklegged tick (*Ixodes scapularis*), lone star tick (*Amblyomma americanum*), and American dog tick (*Dermacentor variabilis*).

The species identified under each of these circumstances were identified as a result of

their occurrence on dogs and cats and the biology/behavior of the ticks.

For a claim against cattle ticks, EPA is proposing testing on either the Southern cattle tick (*Rhipicephalus microplus*) or the cattle fever tick (*Rhipicephalus annulatus*). When presented to the SAP, the SAP noted that if pests of veterinary importance are not the primary objective for this proposal, then pests such as cattle ticks should be removed from the tables. While the emphasis is on pests of significant public health importance and wood-destroying insects due to their significant economic impacts, EPA maintains that cattle ticks should be included in this proposal because of the potential for these ticks to carry diseases such as Texas cattle fever, which can result in significant economic losses to the cattle industry. (Ref. 34) Additionally, the cattle fever tick poses a risk to a small, but highly vulnerable population of humans. Specifically, those people that have had splenectomies are susceptible to a potentially fatal bovine babesiosis infection from an infected cattle fever tick. (Ref. 35).

For a claim against soft ticks, EPA is proposing testing on the species *Ornithodoros hermsi*. Humans typically come into contact with soft ticks when they sleep in rodent infested cabins. The ticks emerge at night and feed briefly while the person is sleeping. The bites are painless, and most people are unaware that they have been bitten. These ticks may transmit tick-borne relapsing fever (*Borrelia hermsii*, *B. parkerii*, or *B. turicatae*).

4. *Scorpions*. In proposed 40 CFR 158.1722, EPA is proposing to require data for a "scorpion" labeling claim due to their venomous sting. In the TSD to the SAP, EPA proposed to only require the striped bark scorpion (*Centruroides vittatus*). For scorpions, EPA is proposing the performance standards under proposed 40 CFR 158.1704.

One public commenter during the SAP questioned why EPA provided only one species for testing, stating that they believed this to be too restrictive. (Ref. 36). EPA chose the striped

bark scorpion as the required test species because it is a larger species of scorpion, and larger species can be harder to kill. Using such a species as the required test species means greater certainty that testing on one species would be representative of testing on other species. The commenter did not provide the name of a species that they consider suitable for testing. The Agency would welcome information to better inform the decision on selection of a suitable test species for scorpions.

5. *Spiders*. In proposed 40 CFR 158.1726, EPA is proposing data requirements for one pest group (Spiders), one pest sub-group (black widow spiders), and five pest-specific spider claims. EPA's current practice for spiders is to require product performance data to be submitted with certain species-specific claims (e.g. "Northern black widow spider"), certain pest-subgroup claims (e.g., "black widow spiders"), or pest-group claims for either "spiders" or "spiders unless the label expressly excludes black widow or brown recluse spiders." The black widow and the brown recluse spiders can deliver bites with potentially serious medical implications, and therefore are considered pests of significant public health importance. Thus, if an applicant submits a draft label with a labeling claim for "spiders (excluding black widow or brown recluse)," the applicant does not need to submit product performance data to EPA with an application for registration. Instead, the applicant would generate product performance data to confirm that the product is effective against these pests and hold those data in their files. In contrast, a general "kill spiders" claim encompasses pests of significant public health importance, i.e., the black widow and brown recluse spiders, and therefore, the applicant would need to submit two product performance studies to EPA to verify this claim, one study each for the brown recluse spider and black widow spider (either Northern black widow spider, the Southern black widow spider, or Western black widow spider).

For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

6. *Centipedes*. In proposed 40 CFR 158.1732, EPA is proposing data requirements for centipedes. EPA proposes testing on either the house centipede, the Florida blue centipede, or on one species from the *Scolopendra* genus. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

The SAP noted that centipedes are generally harmless and considered beneficial insects, behaving as active predators of other arthropod s within structures. Although a species such as the Florida blue centipede (*Hemicolopendra marginata*) can inflict a painful bite, the SAP questioned whether it was sufficient to include centipedes as a pest of significant public health importance. While some species of centipedes may be "harmless," species such as the Florida blue centipede can envenomate with painful bites, which can be categorized as similar to that of a bee sting. Effects can include anaphylactic shock in some individuals. EPA believes that these types of effects are sufficient to be considered as a pest of significant public health importance, and are thus included in this proposed rulemaking.

7. *Lice*. In proposed 40 CFR 158.1736, EPA is proposing data requirements on either the Head louse or the Body louse in order to make a labeling claim against lice. EPA is also proposing a performance standard of 100% for all efficacy claims made against lice. The SAP did not express any opinions on the proposed required test species or performance standards.

8. *Fleas*. In proposed 40 CFR 158.1740, EPA is proposing data requirements for one pest group (Fleas) and six pest-specific claims (cat flea, chigoe flea, dog flea, hen flea, human flea, and oriental rat flea). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Historically, EPA has only required testing on the cat flea in order to make a "flea" claim. The cat flea is common and easy to rear in the laboratory. Additionally, because the cat flea is the most common species that infests pets, most of the available pesticide products target the cat flea.

In the SAP response to the TSD, the Panel suggested adding the oriental rat flea (*Xenopsylla cheopis*) in addition to the cat flea for a "flea" labeling claim. The oriental rat flea (also known as the tropical rat flea) is a vector for bubonic plague (caused by *Yersinia pestis*), which is extremely rare in the U.S. EPA does not believe requiring this additional species provides immediate benefits at this time and would be an additional cost and burden on applicants to provide such data. EPA notes that 40 CFR 158.1709 would cover invertebrate diseases vector claims. In the future, if the plague becomes a significant issue in the U.S., then EPA would consider requiring the submission of data on the oriental rat flea in addition to the cat flea. Since the risk of the oriental rat flea is rare, EPA intends to continue with its existing practice to only require the larger cat flea for a "flea" claim, and is therefore proposing it as the only required test species at this time.

9. *Cockroaches*. In proposed 40 CFR 158.1744, EPA is proposing data requirements for one pest group (cockroaches) and seven pest-specific claims (American cockroach, Australian cockroach, brown cockroach, brownbanded cockroach, German cockroach, oriental cockroach, and the smokybrown cockroach). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For the "Cockroach" pest group claim, EPA has historically required testing on both the American cockroach and the German cockroach, and is proposing to codify this requirement. These are the most common cockroaches requested on product labels and are commonly

controlled to halt the spread of asthma, allergy, and food contamination. The SAP was supportive of these species as the required test species for this pest group claim.

The SAP suggested adding *Periplaneta fuliginosa* and *P. brunnea* (smokybrown and brown cockroach, respectively) to the cockroach pest group. EPA is proposing these pests as a pest-specific labeling claims. Even with these additions, EPA continues to believe that for a general cockroach claim, the German and American cockroach are appropriate representative test species for the overarching pest group.

The Turkestan cockroach (*Blatta lateralis*) is thought to be displacing the Oriental cockroach in the southwestern U.S. and, like other cockroaches, can transfer food-borne pathogens. Because of this development, EPA is adding a pest-specific claim for the Turkestan cockroach to 40 CFR 158.1744.

10. *Keds, Screwworms, and Bot Flies*. In proposed 40 CFR 158.1748, EPA is proposing data requirements for bot flies (excluding human bot fly), the human bot fly, keds, and screwworms. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For bot flies (excluding human bot fly), EPA is proposing to require testing on one of the three following species: horse bot fly, throat bot fly, or the nose bot fly. The SAP suggested specifying the test species as *Gasterophilus* spp. instead of listing three specific *Gasterophilus* species, as specified in the TSD. EPA continues to believe that testing on either the horse bot fly, throat bot fly, or the nose bot fly were the most appropriate for efficacy testing because they are large and can be found throughout the U.S. While they are primarily pests of horses, larvae of these three species may occasionally parasitize humans.

For the human bot fly, EPA is proposing testing on the human bot fly (*Dermatobia*

*hominis*). The human bot fly is not known to vector disease, but the larvae will infest the skin of mammals and live out the larval stage in the subcutaneous layer, causing painful pustules that secrete fluids. The infestation of any fly larvae inside the body is known as myiasis. (Ref. 37). Under bot flies, the SAP stated that human bot fly should be retained as this is frequently introduced by travelers.

In addition to the three proposed options for bot flies, the SAP also suggested EPA consider the *Hypoderma* spp. and *Oestrus ovis* (the sheep bot fly) as additional options. EPA is not proposing to include these species since the Agency has not historically required or received data on these pests. However, EPA requests public comment on whether there is a need to codify product performance data requirements for *Hypoderma* spp. and *Oestrus ovis*.

For screwworms, EPA is proposing to require testing on either the screwworm (*Cochliomyia hominivorax*) or the secondary screwworm (*Cochliomyia macellaria*). The SAP indicated that *Cochliomyia hominivorax* is an eradicated species in the U.S. While EPA acknowledges that the sterile insect eradication program was a success, the species was recently found in Florida. If, in the future, an applicant wanted to make a label claim against screwworms, then *Cochliomyia hominivorax* would be the appropriate test species. Providing this option provides flexibility to the pesticide registrant. (Ref. 38).

For keds, EPA is proposing to require testing on the sheep ked. The sheep ked has historically been the representative species for a “keds” claim, and the SAP expressed general support of the Sheep ked as the required test species. Therefore, EPA is proposing to maintain this practice.

11. *Filth Flies*. In proposed 40 CFR 158.1752, EPA is proposing data requirements for one pest group claim against “Filth flies” and six pest-specific claims (blow fly, cluster fly, face

fly, flesh fly, house fly, and little house fly). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For a "Filth Flies" pest group claim, EPA is proposing to require testing on the house fly (*Musca domestica*) and either one species of flesh fly (*Sarcophaga* spp., *Wohlfahrtia* spp., and other genera of flesh fly) or one species of blow fly (*Phaenicia* spp., *Calliphora* spp., and other genera of blow fly). One public commenter during the SAP questioned why EPA asked for testing in two species. The commenter indicated that for a direct spray application, only testing with the house fly is needed. The commenter suggested that testing with more than one species should only be needed for more specialized claims, such as fly baits. (Ref. 36).

In response, EPA included house flies and the option to select between blow flies and flesh flies because these types of flies move bacteria around from place-to-place when they land. This takes place by touching surfaces, as these flies generally do not bite. "Filth flies" is a large grouping and testing on two species provides greater assurance that the product would be effective against most members of the pest group. House flies are generally the smallest in size of these three groups and therefore may be more susceptible to insecticides. Testing against the larger filth flesh/blow flies reduces the likelihood of overestimating efficacy.

Additionally, the SAP suggested the cluster fly (*Pollenia rudis*) be deleted as a test species. Instead, flies in the genus *Fannia* can be included since they can be relatively easy to rear in laboratory conditions. *Fannia benjamini* complex and *Fannia scalaris* (canyon fly and latrine fly) were specifically mentioned. In response, the cluster fly was not listed as a required test species for a claim against "Filth Flies" in the TSD. The cluster fly was specified as a test species if an applicant makes a pest-specific claim against the cluster fly. Because house flies, blow flies, and flesh flies are considered better representative species for the pest group claim

against "Filth Flies," flies in the genus *Fannia* are not considered a representative alternative to cluster flies.

12. *Mosquitoes*. In proposed 40 CFR 158.1756, EPA is proposing data requirements for a pest group claim against "Mosquitoes." For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704. For the required test species, EPA is proposing that testing be required on at least one mosquito species from three different genera (i.e., one out of three proposed *Culex* spp.; one out of two proposed *Aedes* spp.; and one out of six proposed *Anopheles* spp.).

One public commenter during the SAP asked why the species *Anopheles stephensi* was missing from the list of species for mosquito testing in the TSD, as it is a common, representative lab insect. (Ref. 36). EPA agrees that the *Anopheles stephensi* could be used for testing, and has added *Anopheles stephensi* to the list of species for mosquito testing in EPA's proposal.

Additionally, the SAP comments were much more extensive regarding mosquitoes, as the SAP response covered both required test species as well as how one arrives at conducting the tests to collect the data. These comments are, as follows:

- Suggested having separate tables for killing and repelling and for field and lab testing
- Questioned the suitability of *Culex pipiens* and *C. quinquefasciatus* in repellent studies
- Suggested using *Culex* spp. instead of hybrids *C. pipiens* and *C. quinquefasciatus*
- Indicated *Anopheles freeborni* and *A. punctipennis* are suitable for field testing and not lab testing
- Indicated *Anopheles quadrimaculatus* is not suitable for indoor repellent testing
- Suggested adding *Anopheles albimanus* and *Anopheles stephensi*

• Indicated *Psorophora* is acceptable for field testing

The SAP also noted that for field testing of mosquitoes, certain species provided in EPA's list could not readily be obtained in a field test in the U.S.

In response, EPA agrees that a listing of specific mosquito test species as provided in the TSD was confusing when considered in the context of field testing. With lab testing and semi-field or "caged" testing a particular test species can be selected. The particular species selected for testing could depend on the colonies maintained by the laboratory, as well as the type of product being tested, and EPA believes providing a list of representative species that is comprehensive means that an appropriate species could be identified for a wide variety of product types or claims.

With regards to *Culex pipiens* and *Culex quinquefasciatus*, EPA is aware that these are now considered to be a hybrid mosquito complex. However, EPA believes that retaining the historical names of the *Culex* species provides more appropriate context, given the possibility of more name changes over time.

With regards to *Anopheles* mosquitoes, EPA has provided several species for the applicant to consider because some *Anopheles* mosquitoes may not be appropriate for all types of testing, or colonies of some *Anopheles* mosquitoes may be difficult to maintain in a laboratory. Additionally, EPA is proposing to add *Anopheles albimanus* and *A. stephensi*.

EPA agrees that *Psorophora* might be reported in a field study. Even though this is another genus of mosquito, *Psorophora* is not a major vector of diseases in the U.S. Other species may better inform the decisions that EPA needs to make.

For testing of skin-applied insect repellents, EPA's Guideline 810.3700, entitled, "Insect Repellents to be Applied to Human Skin" provides specific guidance (page 27) on the choice of

field testing sites. (Ref. 39). According to the Guidance, "Field tests for mosquito repellency should be conducted in at least two distinct habitats (e.g., forest, grassland, salt marsh, wetland, beach, barns, or urban environments) where the predominant mosquito species differ."

In field testing, a wide variety of species are encountered. Thus, for field testing, the applicant's submission will provide information on the species captured during the testing. EPA will review the data submitted to determine if a sufficient number and type of species were present. Generally, EPA expects three different genera to be present: *Culex*, *Aedes*, and *Anopheles*.

Claims against specific vector/disease combinations must be supported by testing of the specified vector. Additionally, because mosquitoes are high stakes vectors and because of the difficulty consumers have in differentiating between species, for a claim against any specific species of mosquito, all the required test genera must be tested.

EPA also agrees that certain species of the mosquitoes specified in the TSD might not be obtained in a field test. However, the purpose of providing multiple species is to offer flexibility in how one complies with the data requirements. In the proposal, EPA has not differentiated between what species may be more obtainable in a field versus laboratory test.

Additionally, two commenters provided other comments about how to obtain mosquito data, particularly in relation to using foreign data and foreign species as surrogate data. One commenter, for example, suggested that foreign data be considered acceptable as long as the study is conducted according to the 810.3700 guidelines. (Ref. 40). Another commenter indicated that foreign species could be useful if sufficient colonies of domestic species are not available (e.g., declining colonies of US anopheline mosquito species). (Ref. 41). EPA would like to note that conducting studies according to EPA guidelines is always recommended, but is

not enough to show that a foreign species is an acceptable surrogate for a domestic species. However, the Agency acknowledges that situations may arise where data showing efficacy of a product against foreign species can be useful. Therefore, the Agency will consider bridging data from foreign species to domestic species on a case-by-case basis. With this in mind, EPA is seeking comment on whether other species should be considered as part of the required test species.

13. *Biting Flies*. In proposed 40 CFR 158.1765, EPA is proposing data requirements for the pest group "Biting flies (excluding Sand flies)," the pest sub-groups "Large Biting Flies" and "Small Biting Flies (excluding Sand flies)," and nine pest-specific claims of biting flies. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Since the SAP, the Agency has revised the proposed data requirements to be clearer than initially presented to the SAP. EPA proposed the pest group "Biting flies (excluding Sand flies)" to be consistent with experience on how the Agency receives labeling requests. Sand flies are vectors for Leishmaniasis, a parasitic disease that is found in parts of the tropics, subtropics, and southern Europe which can either cause skin sores or affect several internal organs (usually spleen, liver, and bone marrow). (Ref. 42). This differentiation improves the clarity and is consistent with how products have typically been labeled.

The Agency is also proposing to split the pest sub-groups further into "Large Biting Flies" and "Small Biting Flies (excluding Sand flies)." This is in response to the fact that periodically, the Agency receives requests for claims against large biting flies or claims against small biting flies. This proposal is to provide that flexibility in the codified data requirements.

During the SAP, the Panel suggested that the stable fly (*Stomoxys calcitrans*) and the horn fly (*Haematobia irritans*) be included in the filth fly category. The Panel also questioned

why both species need to be tested. In response, EPA considers both the stable fly and the horn fly to be biting flies. The Agency is proposing stable flies as one of the three representative species for the "Biting Fly (excluding sand flies)" pest group claim and one of the two required test species the "Large Biting Flies" pest sub-group claim. Testing of both species as described in the TSD to obtain a claim against stable flies was an error. Instead, in the absence of an appropriate pest group or pest sub-group representation, the Agency is proposing to require testing against stable flies for a pest-specific efficacy claim against stable flies and testing against horn flies for a pest-specific claim against horn flies.

The SAP suggested adding *Leptoconops kereszi* complex and *L. torrens* (black gnats) to pest sub-group biting midges in the TSD. For claims against biting midges, the Agency was proposing testing against one *Culicoides* species and one *Leptoconops* species. The specific species of *Leptoconops* required are not specified; therefore EPA would consider the species suggested by the commenter (*Leptoconops kereszi* complex and *L. torrens*) to be acceptable. The biting midges pest sub-group has since been revised to be represented as the "Small Biting Flies (excluding Sand flies)" pest sub-group claim. Both biting midges and black gnats are listed separately under the pest-specific claims.

14. *Bed Bugs*. In proposed 40 CFR 158.1768, EPA is proposing data requirements for the pest group claim "Bed bugs" and pest-specific claims for both the Common bed bug and the Tropical bed bug. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For "Bed bugs," one commenter indicated that only one species is important to the vast majority of consumers and thus only one species needs to be tested to support this kind of product registration. For this proposal, EPA agrees that testing to include only the common bed

bug, *Cimex lectularius*, is appropriate as the lone required bed bug test species.

In the TSD, the EPA initially proposed a 95% performance standard for bed bug products. One commenter stated that the performance standard for bed bug control products that claim residual control and ovicidal control should be 90% rather the 95% standard in the TSD. Additionally, the commenter indicated that bed bug products need to have residual activity, because control of bed bugs is not possible via direct contact. They indicated that there must be residual activity in order for the product to claim "control" and if the product does not have residual activity, then this statement should be on the product label. The commenter also stated that a performance standard applicable to bed bug products that claim to kill bed bugs when bed bugs come into contact with a treated surface is needed. Therefore, EPA has decided to propose a performance standard of 90%, instead of the 95% in the TSD.

15. *Conenose Bugs and Kissing Bugs*. For proposed 40 CFR 158.1772, EPA is proposing data requirements for labeling claims against conenose bugs and kissing bugs. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Initially proposed as "True bugs (excluding bed bugs)" in the TSD, EPA is proposing to focus primarily on the two required test species, the conenose bug and the kissing bug. This proposal has now separated them as pest-specific claims since experience has shown that labeling and data are usually submitted with the intent of labeling for the specific pest.

During the SAP, one commenter asked why the common stink bug species is missing from "true bugs." (Ref. 36). In response, the common stink bug is not a disease vector or otherwise a pest of significant public health importance, and therefore EPA did not include it as a test species in the TSD presented to the SAP. Since the "true bug" claims have changed in this group, stink bugs are no longer relevant to this group.

Similarly, the SAP suggested that both the conenose and the kissing bug be required test species. Both the kissing bug and the conenose bug (*Triatoma protracta* and *Triatoma sanguisuga*, respectively) are in the same genus and are both vectors of Chagas disease. Given these similarities and to reduce the number of studies to be submitted, EPA did not believe it was necessary to require both when a "true bug" claim was still in consideration. Based on experience, EPA has since opted to propose that they be separate pest-specific claims.

16. *Ants (excluding carpenter ants)*. In the proposed 40 CFR 158.1776, the EPA is proposing data requirements for pest group "Ants (excluding carpenter ants)," for the pest sub-groups "Fire and Harvester ants," "Fire and Harvester ant colonies," and "Fire ants," and for seven pest-specific claims in the absences of a pest group or sub-group claim.

For colony claims, testing must be done specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on the red imported fire ant (RIFA) (*Solenopsis invicta*), the black imported fire ant (*Solenopsis richteri*) or their hybrid.

Data for the pharaoh ant (*Monomorium pharaonis*) and red imported fire ant (*Solenopsis invicta*) would be required to support a general claim against ants, except carpenter ants. EPA proposes RIFA to receive a claim against fire and harvester ants for direct spray kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed. For colony claims, testing must be specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on, *S. invicta*, *S. richteri*, or their hybrid.

Public comments on the 2013 SAP suggested that additional clarity was needed for categories such as "ants" where only certain members of the group would be considered pests of significant public health importance. (See, e.g., Ref. 40). Similar to EPA's current practice for

spiders, EPA requires product performance data for certain species-specific claims (e.g. “fire ants”) and for general claims against “ants” or “ants, unless certain species are expressly excluded, i.e., fire, pharaoh, harvester, and carpenter ants.” Fire and harvester ants are considered pests of significant public health importance, due to their painful stings that may result in anaphylaxis, while pharaoh ants are considered pests of significant public health importance because they can transfer numerous pathogens much like cockroaches. As discussed separately in more detail in Unit VII.C.18 of this proposal, Carpenter ants are structural pests which also require the submission of efficacy data. As a result, if an applicant submits a draft label with a claim against “ants (excluding fire, pharaoh, harvester, and carpenter ants),” the applicant does not need to provide product performance data to EPA. Instead, the applicant would generate efficacy data to confirm that the product is effective against these non-public health pests and then hold those data in their files. However, a label claim against “ants” encompasses, pests of significant public health importance and structural pests, and therefore for a “kills ants” label claim, the applicant would need to submit at least three product performance studies to EPA to verify this claim, one study each for the fire ant (which can be bridged to cover the harvester ant for a direct spray test), pharaoh ant, and carpenter ant. For a more detailed discussion of the “Carpenter ants” claim, see Unit VII.C.18 of this proposal.

The SAP also suggested adding the following ants to the “Ants (except carpenter ants)” group: European fire ant, odorous house ant, red imported fire ant (RIFA), tropical fire ant, thief ant, dark rover ant, hairy crazy ant, Caribbean crazy ant, yellow crazy ant, pavement ant, and *Crematogaster* spp. Fire ants (*Solenopsis* spp.). Some of the species suggested for inclusion are not pests of significant public health importance (odorous house ant, thief ant, dark rover ant, hairy crazy ant, Caribbean crazy ant, yellow crazy ant, and pavement ant), and thus EPA is not

proposing product performance data requirements specific to these species.

17. *Bees, Wasps, Yellowjackets, and Hornets*. For proposed 40 CFR 158.1780, EPA is proposing data requirement for a pest group claim "Bees, Wasps, Yellowjackets, and Hornets" and pest-specific claim for bald-faced hornet, mud dauber wasp, paper wasp, and yellowjackets. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704. For colony claims against *Vespula* spp. EPA is proposing a performance standard of 100%.

For the pest group claim, EPA is proposing data on two yellowjacket species (one *Vespula* sp. and the bald-faced hornet (*Dolichovespula maculata*)) and one paper wasp (*Polistes* sp.). These required test species were chosen based on their painful stings that may cause life-threatening reactions. The SAP was supportive of the selection of these species as representative to this pest group.

For the pest-specific claims that were proposed, one commenter indicated that stinging bees and wasps, solitary and ground nesting Hymenoptera such as mud daubers, digger wasps/bees, and spider wasps should not be included as pests of significant public health importance. The commenter believed that these females use their stingers for hunting, not defense, which means that it is unlikely such a pest would pose a public health threat. (Ref. 40). Another commenter added that they are also beneficial insects. (Ref. 41). However, these insects can inflict painful stings that may cause life-threatening allergic reactions and therefore are considered pests of significant public health importance and incorporated into the pest-specific claims.

The Asian giant hornet, *Vespa mandarinia,* has recently been sighted in the U.S. At the time EPA developed the pest grouping for "Bees, Wasps, Yellowjackets, and Hornets", this

species was not in the U.S. EPA requests comment on whether there are data to suggest the representative taxa should cover this species, or alternatively, data to suggest the opposite.

18. *Carpenter Ants*. Carpenter ants are structural pests which also require the submission of efficacy data. For proposed 40 CFR 158.1782, EPA is proposing data requirement for a pest group claim "Carpenter Ants." For the pest group claim, EPA is proposing requiring testing data on one of the following carpenter ant species: black carpenter ant (*Camponotus pennsylvanicus*), or Florida carpenter ant (*Camponotus floridanus*), or Western carpenter ant (*Camponotus modoc*).

For bait treatment EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment," EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

For carpenter ants, the SAP suggested adding the carpenter ant (*Camponotus neracticus*) as a test species. The Panel also indicated that more test species might be needed on the list because laboratories may experience hardship obtaining and maintaining colonies of some of the species on the list provided. In response EPA notes that there are three carpenter ant options for testing and that testing would need to be done on only one of the species. EPA notes that the *Camponotus neracticus* is significantly smaller than any of the three options. Thus, EPA believes that the three proposed test species are better choices for representative species.

19. *Wood-destroying beetles*. For proposed 40 CFR 158.1784, EPA is proposing data requirements for wood destroying beetles. For products making a claim against wood-destroying beetles or wood-boring beetles, EPA is proposing to require testing on three species: anobiid

beetle (*Anobiidae* sp.), bostrichid beetle (*Bostrichidae* sp.), and old house borer (*Hylotrupes bajulus*). For products making a claim against true powderpost beetles, EPA is proposing to require testing on one species from the Lyctinae subfamily.

For bait treatment EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment," EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

One public commenter suggested that EPA consider adding a fourth genus also known as the lyctid beetles (Lyctinae spp.) to represent the major wood-destroying beetle genera while allowing flexibility to test three of the four. (Ref. 43). The EPA does not believe that substituting a lyctid beetle as a representative test species is appropriate, as these beetles are not likely to cause structural damage.

20. *Termites*. For proposed 40 CFR 158.1786, EPA is proposing data requirements for the subterranean termite, desert subterranean termite, Formosan subterranean termite, drywood termite, and dampwood termite. For products making a claim against termites, EPA is proposing testing on species from four genera of termites. EPA is proposing to require testing on:

• *Coptotermes formosanus*

• And one of the following *Reticulitermes* species: *Reticulitermes flavipes*, or *Reticulitermes hesperus*, or *Reticulitermes virginicus*

• And one of the following arboreal termite species: *Nasutitermes coringer* (Motschulsky)

• And one of the following drywood termite species: *Cryptotermes brevis*, or

*Cryptotermes cavifrons*, or *Incisitermes minor*, or *Incisitermes snyderi*

For a claim against arboreal termites, EPA is proposing testing of one arboreal termite species: *Nasutitermes coringer* (Motschulsky). For a claim against dampwood termites, EPA is proposing testing of the following dampwood termite: *Zootermopsis* sp. For a claim against drywood termites, EPA is proposing testing of one of the following drywood termites: *Cryptotermes brevis*, or *Cryptotermes cavifrons*, or *Incisitermes minor* or *Incisitermes snyderi*. For a claim against subterranean termites, including formosan subterranean termites, EPA is proposing testing in two genera of termites. Specifically, EPA is proposing testing on the following *Coptotermes* species: *Coptotermes formosanus*; and one of the following *Reticulitermes* species: *Reticulitermes flavipes*, or *Reticulitermes hesperus*, or *Reticulitermes virginicus*.

For bait treatment, EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment" EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

The SAP suggested adding drywood termite (*Incisitermes synderi*) as a test species. EPA is proposing to add *Incisitermes snyderi* to the list of representative species for drywood termites. Additionally, *Cryptotermes cavifrons*, a species endemic to Florida, would also be an acceptable representative test species and EPA is proposing to add this organism as well.

The SAP and other commenters questioned the standard of "100% prevention of damage to wood" and thought that the lesser 95% or 90% would be more acceptable. EPA agrees with the comment and is proposing a 95% prevention of damage to wood standard. However, EPA

notes that what constitutes a 95% standard is dependent on the type of study being performed. For example, for the standard U.S. Forest Service Concrete Slab field study, the 95% would be calculated such that any damage greater than nibbles to surface etching would be considered a failure; if a single plot had more than one instance of nibbles to surface etching in any of the standard five evaluation periods, this would also be a failure. A 95% success rate for the U.S. Forest Service Concrete Slab (CS) tests would be determined by the combined data for a product, by rate, in a given year. For non-structural wood preservative treatments, EPA is proposing a standard of 100% prevention of damage to wood for $\geq 2$ years. Additionally, to be consistent with the majority of other pests, EPA is proposing the termite standards for direct applications to pests, surface applications, and spatial applications will be changed to a performance standard of 90%, consistent with proposed 40 CFR 158.1704.

21. *Invasive Species*. EPA believes treating invasive species quickly and appropriately is critical, and EPA does not intend to preclude use of a pesticide product pursuant to FIFRA 2(ee) to treat an invasive species. EPA believes that pesticide products are an important tool for managing the spread of an invertebrate invasive species and the related public health concerns or significant economic impacts. The availability of pesticide products with proven performance against an invasive species is important to slowing the spread of the invasive species.

Due to the sudden appearance and often rapid spread of invasive species, except for the pests noted, 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 pests will be considered on a case-by-case basis. Given the expectation of infrequent submission of such an application, a "case-by-case" approach is the most suitable. EPA recommends that applicants consult with the

Agency when first considering a submission to place an invasive species on the label of a pesticide product. As part of the consultation, EPA would be able to provide information on protocol development and selection of test species. EPA generally expects to require product performance data for invasive species that are similar to the Asian longhorned beetle and emerald ash borer in that they have the potential to cause significant economic or ecological damage and the efficacy of products used against them cannot readily be determined at the time of application.

This proposal specifies that the Asian longhorned beetle and the emerald ash borer are two invasive pests for which product performance data must be submitted. The efficacy of the products used for their control typically cannot be determined until the season after application, and the EPA believes it appropriate to continue the practice of reviewing efficacy data for these invasive species.

**VIII. Updates to Subparts U and V**

In addition to the inclusion of product performance data requirements under the new subpart R, EPA is also proposing to revise and update the product performance data requirements language for biochemical and microbial pesticides in subpart U, 40 CFR 158.2070 and subpart V, 40 CFR 158.2160, in order to clarify the requirements for products that would be subject to both proposed subpart R and also subpart U or subpart V.

Subpart U (biochemical pesticides) and subpart V (microbial pesticides) currently require that product performance data be developed, and that each applicant must ensure through testing that the pesticide product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Both subparts also state that EPA may require, on a case-by-case basis, submission of product performance data for any pesticide product registered

or proposed for registration or amendment (see, 40 CFR 158.2070 and 40 CFR 158.2160). These requirements would not be modified by this proposal.

Subpart U (biochemical pesticides) and subpart V (microbial pesticides) also currently require that product performance data be submitted for each biochemical and microbial pesticide product that bears a claim to control public health pests, as the term is used in subparts U and V. This requirement is followed by a non-exhaustive list of public health pests. This includes pest microorganisms infectious to humans in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans.

This proposal adds additional clarity by including a provision in subpart U (biochemical pesticides) and subpart V (microbial pesticides) stating that product performance data must be submitted for each product that bears a claim against an invertebrate pest that is covered by subpart R. This provision is intended to be coextensive with the requirements of subpart R, and broader than the currently existing requirements in subparts U and V related to “public health pests” in that it would also cover the wood-destroying beetles and invasive exotic species claims covered by subpart R.

Additionally, EPA notes that data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case pursuant to the provisions in 40 CFR 158.45 and 40 CFR 158.1707.

## IX. Impact of this Proposal on Future and Existing Registrations

This action, if finalized, will have no immediate effect on existing registrations unless new information indicates an existing registration includes claims that are not sufficiently

supported. When an application for registration or amended registration requests to put a claim(s) on its pesticide product's labeling for effectiveness against an invertebrate species that is covered by this action, the application would generally include submission of product performance data to support those claims for effectiveness.

## X. Peer Review

### *A. Human Studies Review Board*

1. *Background*. Research with human subjects that is conducted or supported by the U.S. government is subject to regulations for the protection of human subjects. These regulations are referred to as the Common Rule. EPA's codification of the Common Rule appears at 40 CFR part 26, subpart A. On February 6, 2006 (71 FR 6138) (FRL-7759-8), EPA published a final rule amending part 26 by adding new subparts (B-Q). This amendment added, among other parts, Subpart K, which applies standards similar to those in the Common Rule to third parties (i.e., those other than federal agencies and federally-funded researchers) conducting research with human subjects. Additional amendments to part 26 have been made, most recently in 2019 (84 FR 35315, July 23, 2019) (FRL-9996-48-ORD). Under EPA's regulation, if the research involves intentional exposure of a human subject and if the sponsor or investigator intends to submit the results of the research to EPA in connection with any action that may be performed by EPA under the pesticide laws (FIFRA or FFDCA), then the research must comply with the provisions of 40 CFR part 26; the requirements of EPA's human studies rule also apply to any research involving intentional exposure of a human subject to a pesticide, when the results are intended to be submitted in connection with a regulatory action under any other statute EPA administers. In addition to establishing protections for human subjects of research, EPA established the Human Studies Review Board (HSRB or Board) to review both proposals for

new research and reports of covered human research on which EPA proposes to rely under the pesticide laws. The HSRB is a federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.2, section 9).

The HSRB typically includes independent experts in toxicology, exposure assessment, industrial hygiene, statistics, and bioethics, as well as an entomologist consultant. The HSRB provides EPA with advice, information, and recommendations on issues related to both the scientific and ethical aspects of human subjects research. The major objectives are to provide review and recommendations on the scientific and ethical aspects of research proposals and protocols, and reports of completed research with human subjects; and, when requested, advise on how to strengthen EPA's programs for protection of human subjects of research. EPA considers all recommendations from the HSRB before finalizing its reviews of proposed or final research.

The HSRB reports to the EPA Administrator through EPA's Science Advisor. Since 2006, the rigorous independent reviews conducted by EPA and the HSRB, as mandated by part 26, have resulted in research protocols designed to result in scientifically-sound data and to ensure the protection of human subjects involved in the research. In providing for the establishment of the HSRB, the regulations have reassured the public that all pesticide research involving intentional exposure to human subjects undergoes thorough independent and expert review based on scientific and ethical standards.

Under 40 CFR part 26, subpart K, protocols for research subject to the regulation’s requirements must be submitted to EPA for review and evaluation before initiation of the study. The relevant information that must be included in the proposed research protocol is specified in 40 CFR 26.1125. EPA then evaluates the protocol and makes a determination about the scientific

validity and reliability of the research as well as examining the ethical aspects of the research, in accordance with the conditions in 40 CFR 26.1603. EPA submits the protocol and supporting materials, as well as EPA's science and ethics reviews of the proposed research to the HSRB for review and comment. The members of the HSRB review the proposed research. Then in an open and transparent manner at a public meeting, members of the HSRB ask additional questions, provide their individual comments, and participate in a discussion which is documented in meeting minutes. Each final HSRB report contains the Board's responses to charge questions posed by EPA, as well as the final, approved advice of the HSRB. The research cannot be initiated until EPA approves the protocol, following its consideration of the HSRB's input and recommendations. The protocol will only be approved if EPA determines that the research conducted according to the protocol would meet the standards of 40 CFR 26, Subparts K and L. Information on the HSRB, including materials reviewed and recommendations can be found on the HSRB webpage. (Ref. 44).

Once the research has been conducted, then all of the records relevant to the research, including raw data and records of ethical review, are submitted to EPA. EPA examines all submitted materials, considers the scientific and ethical conduct of the research, and provides the completed research and its evaluation of the completed research to the HSRB. The HSRB reviews the documents and discusses them at a public meeting in the same open and transparent manner. The HSRB issues a report of their findings following the meeting. EPA may rely on the results of completed human research involving intentional exposure of human subjects only if the research meets the standards referenced in part 26, subpart Q.

2. *Review of EPA's draft guideline 810.3700*. In October 2008, EPA presented to the HSRB a draft guideline titled "Insect Repellents to be applied to Human Skin" for review and

evaluation. (Ref. 46). The HSRB final report (Ref. 46) for that October 2008 meeting included the HSRB's comments and concerns about the statistical analysis plan included in the draft guideline.

Based on the HSRB review and comments, EPA revised the guideline and presented the revised guideline to the HSRB on June 23, 2010. EPA's Senior Policy Advisor for the Pesticide Program made a presentation titled, "OPP Policy Decisions Regarding Insect Repellent Efficacy Testing." (Ref. 31).

The HSRB recommended several changes or clarifications for the revised guideline in its final report, (Ref. 47) including:

• Removal of the maximum-likelihood method requirement in the data analysis section;

• Clarification of recommendations regarding the use of positive controls, particularly with respect to the number of controls and the rationale for including them in the study;

• Careful consideration of recommendations regarding the recruitment and inclusion of so-called 'vulnerable' populations; and

• Encouraging the use of study designs that will enable investigators to collect data that will allow quantitative measurement of repellent efficacy in addition to determining the complete protection time (CPT).

On August 6, 2010 (75 FR 47592), EPA announced the availability of the final guideline for Insect Repellents to be Applied to Human Skin (Guideline 810.3700).

3. *Overall impact of HSRB review*. As required by 40 CFR part 26, the HSRB has reviewed and commented on all protocols for conducting skin-applied insect repellents as well as the completed studies conducted according to those protocols. In its final reports, the HSRB provided recommendations to strengthen EPA's statistical approaches for calculating CPTs.

Additionally, the HSRB's feedback has resulted in EPA's development of a model to calculate sample sizes for field and lab testing with mosquitoes and lab testing with ticks, to support results. At the recommendation of the HSRB, EPA also elected not to require positive controls.

*B. FIFRA Scientific Advisory Panel*

On March 19-20, 2013, EPA presented to the SAP a variety of issues for their consideration and response concerning the Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2012-0574. Unit VII of this proposal discusses how comments from the SAP and public comments informed the data requirements of proposed subpart R.

In separate actions EPA has developed and revised testing guidelines and continues to do so. While this rule refers to these guidelines, and recommends their use, they are not the subject of today's proposal. For informational purposes, EPA is providing a description of SAP meetings relevant to those guidelines.

1. *1994 meeting*. In 1994, EPA held a 2-day meeting of the SAP to review the Agency's proposed amendments to the data requirements for pesticide registrations contained in 40 CFR part 158. The SAP was asked to comment on each data requirement and identify, in their opinion, which ones were necessary to fully and thoroughly evaluate the potential hazard of a chemical compound and which ones were not intrinsically useful in providing practical scientific information. The review included both comparative product performance data requirements along with product performance data requirements for public health and non-public health data

requirements. A very complete discussion of the 1994 SAP was presented in the proposed rule for conventional pesticides (March 11, 2005; 70 FR 12310) (FRL-6811-2).

2. *April 2000 meeting*. In April 2000 the SAP was asked to comment on a draft guideline regarding insect repellents for human skin and outdoor premises. (Ref. 48).

3. *July 2002 meeting*. On July 30-31, 2002, the SAP was asked to review the design and scientific soundness of the draft guideline entitled "Termite Bait Testing." EPA's presentations, the draft guideline, the charge questions, and the Panel's review of the guideline are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2002-0125.

4. *March 2012 meeting*. On March 6-7, 2012, EPA presented to the SAP, a draft guideline regarding bed bugs. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2011-1017. After taking the SAP's feedback into consideration, EPA announced the availability of the final test guideline, Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products; OCSPP Test Guideline 810.3900, on June 14, 2017 (82 FR 27254) (FRL-9959-78).

5. *May 2018 meeting*. On May 8-10, 2018, EPA presented to the SAP for their consideration and response scientific issues associated with proposed revisions to two EPA Test Guidelines 810.3100 (Soil Treatment for Imported Fire Ants), and Guideline 810.3500 (Premises Treatment), for Red Imported Fire Ants (RIFA). These guidelines were originally published in March 1998.

The proposed premises treatment guideline revisions presented to the SAP contained recommended test methodologies for a wide range of products intended to kill, control, flush, and/or knockdown invertebrate premises pests, such as cockroaches, ticks, mosquitoes, flies, and

wasps. The guideline did not cover treatment of livestock or pets, wide area-mosquito control, or bed bug products. In addition to guidance for testing efficacy of direct pesticide application to pests, residual treatments, and cockroach and fly baits in the laboratory, the proposed guideline also included field testing methods for outdoor misting systems, Hymenoptera nest treatments, and outdoor foggers. Methods for resistance ratio determination and characterization of pest population strain susceptibility were also described.

The proposed RIFA treatment guideline revisions contained recommended test methodologies for evaluating the performance of pesticide products for the treatment and control of red imported fire ant colonies/mounds. The guideline did not cover premises treatments for RIFA workers/foragers, such as direct application to pests. Field tests for both mound- and area-applied pesticide products were proposed, along with accompanying laboratory studies for baits, barrier treatments, and insect growth regulators.

The meeting announcement, the Agency's presentations and support documents, and public comments are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2017-0693. In September of 2019, EPA published the final Product Performance Test Guidelines OCSPP 810.3500: Premises Treatments; Background information, the draft guideline, and charge questions developed by EPA are available at *https://archive.epa.gov/scipoly/sap/meetings/web/html/040500_mtg.html*.

7. *June 2019 meeting*. On June 11-14, 2019, the SAP reviewed EPA's proposed guidelines for Efficacy Testing of Topically Applied Pesticides Used Against Certain Ectoparasitic Pests on Pets. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-20190161.

## XI. Request for Comments

The Agency invites the public to provide comment on the proposed requirements and their basis. Specifically included within the Agency's requests for comments are suggestions which can be supported by scientific data for the Agency to consider during the development of the final rule. Specific comments are requested for:

1. *Definitions*. The Agency welcomes comment on the proposed definitions. The Agency also welcomes suggestions on additional definitions that may be needed to help clarify what is required in the regulations.

2. *Representative test species*. The proposed rule includes taxonomic categories of invertebrates which require more than one species to be tested to support a general claim for that pest group. The representative taxa were selected on the basis of vigor of the pest species and the likely ability of the species to serve as an adequate surrogate for other pests in the group. The selection of representative taxa was informed by the 2013 SAP.

3. *Performance standards*. The Agency welcomes specific comments on performance standards. The Agency would need to see scientifically sound data to support any recommendations for performance standards that differ from those proposed. The Agency believes requiring data showing the pesticide meets a specified threshold level (performance standard) of efficacy is the best means of addressing potential consequences which could occur through the use of ineffective pesticides intended for use against pests that transmit disease.

4. *Economic analysis*. The Agency also welcomes public comment on its economic analysis of the proposed rule, as well as on its underlying assumptions, economic data, and high and low-cost options and alternatives. Describe any assumptions and provide any technical information and data used in preparing your comments. Explain estimates in sufficient detail to

allow for it to be reproduced for validation. EPA's underlying principle in developing the proposed revisions has been to strike an appropriate balance between the need for adequate data to make the statutorily mandated determinations and informed risk management decisions, while minimizing data collection burdens on regulated community required to support product performance data requirements. In particular, EPA would appreciate public comment on the magnitude of the savings in discovery costs discussed on page 29 of the cost analysis.

## XII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. US EPA. Cost Analysis of the Proposed Product Performance Rule, prepared by the Biological and Economic Analysis Division, Office of Pesticide Programs, available in docket: EPA-HQ-OPP-2020-0124.

2. US EPA. Pesticide Registration (PR Notice) Notice 2002-1, available at https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf at 2 (accessed March 6, 2020); *see also* Public Review Draft: Pesticide Registration (PR Notice) 2020-[X], Draft List of Pests of Significant Public Health Importance—Revised 2020, docket EPA-HQ-OPP-2020-0260.

3. US EPA. PRN 96-7 Termiticide Labeling, available at https://www.epa.gov/pesticide-registration/prn-96-7-termiticide-labeling (accessed March 13, 2020).

4. United States Public Health Service. Public Health Report. 1923 Aug 3; 38(31): 1747–1814.

5. Scott, Thomas and Willem Takken. Feeding strategies of anthropophilic mosquitoes result in increased risk of pathogen transmission. Trends in Parasitology March 2012, Vol. 28, No. 3.

6. Eisen, Lars. Pathogen transmission in relation to duration of attachment by Ixodes scapularis ticks, Ticks and Tick-borne Diseases.

7. US EPA. Bed Bugs, Get them out and Keep them Out, available at https://www.epa.gov/bedbugs (accessed March 6, 2020).

8. US EPA and CDC. Joint statement on bed bug control in the United States from the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Environmental Protection Agency (EPA); available at https://stacks.cdc.gov/view/cdc/21750/Email (accessed March 19, 2020).

9. Su N-Y, Scheffrahn RH (2000). Termites as pests of buildings. In: Abe T, Bignell DE, Higashi M (eds) Termites: evolution, sociality, symbioses, ecology. Kluwer, Boston, pp 437–453.

10. Peterson CJ, Wagner TL, Shelton TG, Mulrooney JE (2008). A historic pest: 90 years of USDA publications reveal changes in termite management. Pest Manag Prof 76(2):25, 28–30, 32.

11. US EPA. Office of Pesticide Programs, Label Review Manual, available at *https://www.epa.gov/pesticide-registration/label-review-manual* (accessed March 13, 2020).

12. US EPA. Product Performance Guideline 810.1000, Overview, Definitions, and General Considerations, available at https://www.epa.gov/test-guidelines-pesticides-and-toxic-

substances/series-810-product-performance-test-guidelines (accessed March 6, 2020).

13. CDC. Division of Vector Borne Infectious Diseases: West Nile Virus Fact Sheet available at https://www.cdc.gov/westnile/resources/pdfs/wnvFactsheet_508.pdf, (accessed March 9, 2020).

14. CDC. Zika Virus, Statistics and Maps; available at https://www.cdc.gov/zika/reporting/index.html (accessed March 6, 2020); CDC, Zika Virus, available at https://www.cdc.gov/zika/index.html (accessed March 6, 2020).

15. CDC. Lyme Disease: Data and Surveillance, available at https://www.cdc.gov/lyme/datasurveillance/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Flyme%2Fstats%2Findex.html (accessed March 19, 2020).

16. M. L. Wilson, J. F. Levine, and A. Spielman. Effect of deer reduction on abundance of the deer tick (*Ixodes dammini*), Yale J Biol Med. 1984 Jul-Aug; 57(4): 697–705.

17. David Cameron Duffy, Scott R. Campbell, Dara Clark, Chris Dimotta, Susan Gurney. *Ixodes scapularis* (Acari: Ixodidae) Deer Tick Mesoscale Populations in Natural Areas: Effects of Deer, Area, and Location, Journal of Medical Entomology, Volume 31, Issue 1, 1 January 1994, Pages 152–158, https://doi.org/10.1093/jmedent/31.1.152.

18. CDC. Lyme Disease: Treatment, available at https://www.cdc.gov/lyme/treatment/index.html (accessed March 6, 2020)

19. CDC. Signs and Symptoms of Untreated Lyme Disease, available at http://www.cdc.gov/lyme/signs_symptoms/index.html *(accessed March 9, 2020).*

20. CDC. Rocky Mountain Spotted Fever: Signs and Symptoms, available at https://www.cdc.gov/rmsf/symptoms/index.html, (accessed March 6, 2020); CDC.

21. CDC. Rocky Mountain Spotted Fever: Information for Health Care Providers,

available at https://www.cdc.gov/rmsf/healthcare-providers/index.html (accessed March 6, 2020).

22. CDC. Lyme Disease: Preventing Tick Bites on People, available at https://www.cdc.gov/lyme/prev/on_people.html *(*accessed March 6, 2020).

23. CDC. Division of Vector Borne Infectious Diseases: West Nile Virus (WNV) Fact Sheet https://www.cdc.gov/westnile/resources/pdfs/wnvFactsheet_508.pdf (accessed March 6, 2020).

24. Emerald Ash Borer Information Network, available at http://www.emeraldashborer.info/about-eab.php (accessed March 9, 2020)

25. USDA. Emerald Ash Borer, available at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-and-diseases/emerald-ash-borer (accessed March 9, 2020).

26. USDA. Asian Long-Horned Beetle, available at https://www.invasivespeciesinfo.gov/profile/asian-long-horned-beetle, (accessed March 9, 2020).

27. NRS. Economic Impacts of Non-Native Forest Insects in the Continental United States, available at https://www.nrs.fs.fed.us/pubs/38719 (accessed March 9, 2020).

28. US EPA. Technical Support Document Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance Submitted to the FIFRA Scientific Advisory Panel for Review and Comment March 19-21, 2013 (Hereinafter “TSD"), available in docket: EPA-HQ-OPP-2012-0574-0002, Appendix 1, Tables I and II.

29. US EPA. FIFRA Scientific Advisory Panel, Meeting Minutes and Final Report for the

March 19-21, 2013 Scientific Advisory Panel, available at https://www.epa.gov/sites/production/files/2015-06/documents/031913minutes.pdf (accessed April 9, 2020).

30. World Health Organization (WHO). Guidelines for Efficacy Testing of Mosquito Repellents for Human Skin, available at http://whqlibdoc.who.int/hq/2009/WHO_HTM_NTD_WHOPES_2009.4_eng.pdf (accessed March 23, 2020).

31. US EPA. OPP Policy Decisions Regarding Insect Repellent Efficacy Testing, (prepared for June 23, 2010, Human Subjects Research Board Meeting.)

32. USDA. National Invasive Species Information Center, available at https://www.invasivespeciesinfo.gov/ (accessed April 29, 2020).

33. Consumer and Specialty Products Association (CSPA). Comment submitted by Beth Law, CSPA, March 15, 2013, EPA-HQ-OPP-2012-0574-0014.

34. USDA. Victor Borne Diseases: Cattle Fever Ticks, available at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/cattle-vector-borne-diseases (accessed March 9, 2020).

35. Bovine Babesiosis, available at cfsph.iastate.edu/factsheets/pdfs/bovine_babesiosis.pdf (accessed March 24, 2020).

36. S.C. Johnson & Son, Inc. Comment submitted by Jill Geyser, S.C. Johnson & Son, Inc., March 9, 2013, EPA-HQ-OPP-2012-0574-0011.

37. UF IFAS. Featured Creatures: Human Bot Fly, available at http://entnemdept.ufl.edu/creatures/misc/flies/human_bot_fly.htm (accessed March 9, 2020).

38. USDA. National Agricultural Library, New World Screwworms, available at

https://www.nal.usda.gov/exhibits/speccoll/exhibits/show/stop-screwworms--selections-fr/introduction (accessed March 9).

39. US EPA. EPA's Guideline 810.3700, entitled, "Insect Repellents to be Applied to Human Skin," available at https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines (accessed July 1, 2020).

40. Comment submitted by Dudley Hoskins, Responsible Industry for a Sound Environment, March 10, 2013, EPA-HQ-OPP-2012-0574-0009.

41. Comment submitted by Beth Law, Consumer and Specialty Products Association, March 15, 2013, EPA-HQ-OPP-2012-0574-0014.

42. CDC. Parasites- Leishmaniasis, available at https://www.cdc.gov/parasites/leishmaniasis/index.html (accessed March 16, 2020).

43. Comment submitted by Brian Forschler, Termiticide Scientific Review Panel, March 19,2013, EPA-HQ-OPP-2012-0574-0016.

44. US EPA. Science Adviser Programs: Human Studies Review Board, available at https://www.epa.gov/osa/human-studies-review-board (accessed April 1, 2010).

45. US EPA. Draft Guideline 810.3700, Insect Repellents to be applied to Human Skin https://archive.epa.gov/osa/hsrb/web/pdf/guidelines-for-performance-testing-of-skin-applied-insect-repellents-9.23.08.pdf (accessed April 1, 2020).

46. US EPA. October 21-22, 2008 EPA Human Studies Review Board Meeting Report, available at https://archive.epa.gov/osa/hsrb/web/pdf/october2008hsrbbfinaldraftreport12808.pdf (accessed April 9, 2020).

47. US EPA. EPA Human Studies Review Board Meeting Report, June 23, 2010. Available at https://archive.epa.gov/osa/hsrb/web/pdf/june2010finalreport090910.pdf (accessed

April 14, 2020).

48. US EPA. Background Information, the Draft Guideline, and Charge Questions Developed by EPA, available at *https://archive.epa.gov/scipoly/sap/meetings/web/html/040500_mtg.html*.

49. US EPA. "Proposed Rule-related ICR Amendment for Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests" (RIN 2070-AJ49), EPA ICR No.: 0277.20 and OMB Control No.: 2070-[tbd]. November 2020.

## XIII. FIFRA Review Requirements

Pursuant to FIFRA section 25(a), EPA submitted the draft proposed rule to the Secretary of Agriculture (USDA) and the FIFRA SAP for review. A draft of the proposed rule was also submitted to the appropriate Congressional Committees.

## XIV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action (Ref. 1) which is summarized in more detail in Unit I.E. This analysis is available in the docket.

### *B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs*

This action is expected to be a deregulatory action under EO 13771 (82 FR 9339, February 3, 2017). Details on the estimated cost savings of this proposed rule can be found in EPA's cost analysis (Ref. 1).

*C. Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document that EPA prepared is assigned EPA ICR No. 0277.20 and OMB Control No.: 2070-[tbd] (Ref. 49). You can find a copy of the ICR in the docket and it is briefly summarized here.

The information collection activities in this proposed rule are associated with the codification of efficacy data requirements against certain invertebrate pests. These information collection activities are activities associated with the application for a new or amended registration of a pesticide and are currently approved by OMB under OMB Control No. 2070-0060 (EPA ICR No. 0277). As such, this ICR is intended to amend that existing ICR at the final rule stage, incorporating the information collection activities attributable to this proposed rule, including a reduction in transaction costs associated with a clear codification of the product performance data requirements for certain invertebrate pests.

*Respondents/affected entities:* There are three groups impacted by the rule. Chemical producers (NAICS 32532), colleges, universities, and professional schools (NAICS code 611310), and research and development labs and services (NAICS code 541712).

*Respondent's obligation to respond:* These data must be submitted for the applicant to receive the desired pesticide registration or label claim. Authorizing legislation is contained in Section 3 of FIFRA (7 U.S.C. 136). The implementing regulations specific to the product

performance data requirements are contained in 40 CFR part 158.

*Estimated number of respondents:* EPA estimates that registrants submit 60 data packages to the Agency annually for efficacy review. Some registrants may submit multiple data packages per year. Under this rule the number of submissions may decline – and therefore the number of respondents may also decrease.

*Frequency of response:* On occasion

*Total estimated burden:* The proposed rule is expected to reduce burden hours by 4,683 annually, including 4,515 hours from reduced paperwork burden associated with data generation and 168 hours from reduced paperwork burden associated with the application process. Burden is defined at 5 CFR 1320.3(b). EPA already accounts for the activities associated with the proposed rule in the currently approved ICR, which covers most activities associated with new and amended registrations; EPA estimates a total annual respondent burden of 1.5 million hours for all these activities. As discussed in the Proposed Rule-related ICR Amendment (Ref. 49), 483,000 of those hours are paperwork burden from data generation for new products, and 102,000 of those hours are paperwork burden from application for new and amended products.

*Total estimated cost:* The estimated burden reduction is expected to reduce burden cost by $330,000 annually, including $315,000 from reduced paperwork burden associated with data generation and $15,000 from reduced paperwork burden associated with the application process, which includes $0 annualized capital or operation and maintenance costs. EPA already accounts for the activities associated with the proposed rule in the currently approved ICR, which covers most activities associated with new and amended registrations; EPA estimates a total annual respondent burden of $109 million for all these activities. As discussed in the Proposed Rule ICR (Ref. 49), $33.7 million of that cost is paperwork burden from data generation for new products,

and $9.3 million of that cost is paperwork burden from application for new and amended products.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA.

*D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq*. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. EPA's small entity analysis suggests that the greatest impact, and the most potential cost savings, would accrue to small entities and new registrants. While large, established registrants have experience with the registration process and are aware of EPA's data requirements or have the means to determine the appropriate studies, new and small registrants without that experience may bear significant costs of acquiring this information. The registrants would have easier access to the data requirements, and the reduction in information acquisition costs would be largest for those registrants with the greatest

information acquisition needs. Thus, EPA anticipates that the proposed rule would result in cost savings, particularly for small and first-time registrants. While the affected NAICS codes contain up to 5,438 small entities, EPA does not expect all entities to experience cost savings in all years as a result of this proposed rule. As the cost analysis (Ref. 1) describes, a sample of 30 applications was selected at random. These applications were submitted by 16 different firms, four of which EPA was able to identify as small businesses according to the Small Business Administration Employees or Revenue Thresholds. About 60 packages are received annually by EPA for control claims. Therefore, EPA expects that, on average, approximately ten small entities will experience cost savings each year as a result of this proposed rule.

While not every element of the proposed rule would result in savings for registrants, EPA conservatively estimates that the rule would result in $1 million in annual reductions in registrant expenditures on the process of receiving label claims against public health, wood destroying, and invasive species pests, equivalent to about $17,000 in savings per data package submitted to the Agency and about $5,500 per registrant in annual savings I have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities. The basis for this determination is presented in the small entity analysis prepared as part of the cost analysis for the proposed rule (Ref. 1), which is summarized in Unit I.E, and a copy is available in the docket for this rulemaking. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and will not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. The proposed rule would primarily

affect the private sector, i.e., pesticide registrants. The rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, or 205 of UMRA. The cost analysis for this action is summarized in Unit I.E. and is available in the docket.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

*G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. At present, no Tribal governments hold, or have applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this action.

*H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered

regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

*J. National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

*K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

**Lists of Subjects in 40 CFR Part 158**

Environmental protection, administrative practice and procedure, agricultural and non-agricultural, pesticides and pests, reporting and recordkeeping requirements.

Dated: _____.

**Andrew Wheeler,**

*Administrator.*

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 158 as follows:

**PART 158 - [AMENDED]**

1. The authority citation for part 158 continues to read as follows:

**Authority**: 7 U.S.C. 136-136y; 21 U.S.C. 346(a)

**PART 158 DATA REQUIREMENTS FOR PESTICIDES**

2. In § 158.1, revise paragraph (c) to read as follows:

**§ 158.1 Purpose and scope.**

***  *  *  *  ***

(c) *Scope of individual subparts*.

(1) *Conventional pesticides*. Subparts A, B, C, D, E, F, G, K, L, N, O, and R apply to conventional pesticides.

(2) *Biochemical pesticides*. Subparts A, B, E, R, and U apply to biochemical pesticides.

(3) *Microbial pesticides*. Subparts A, B, E, R, and V apply to microbial pesticides.

(4) *Antimicrobial pesticides*. Subparts A, B, C, D, E, R, and W of this part apply to antimicrobial pesticides.

3. Revise the heading for subpart E to read as follows:

**Subpart E—Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins**

4. Add section subpart R to read as follows:

**Subpart R—Product Performance for Products Claiming Effectiveness Against Invertebrate Pests**

Sec.



## Subpart R—Product Performance for Products Claiming Effectiveness Against Invertebrate Pests

### § 158.1700 General requirements.

(a) *General*. Each applicant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, as specified herein and on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(1) *Test substance*. All product performance testing is performed using the end-use product.

(2) *Test organism*. All product performance testing must report the species tested.

(3) *Testing*. All products are to be tested to support the claim(s) made on the labeling of the pesticide product.

(4) To determine the specific product performance data required to support the registration of each pesticide product, the applicant must refer to the applicable sections of this subpart.

(b) *Product performance data submission*. Each product that bears a claim subject to this subpart, must be supported by submission of product performance data, as listed in this subpart. This product performance data must be submitted with any application for registration or amended registration. For the pest-specific claims listed in this subpart, data must be for the species specified to support the claim.

**§ 158.1701 Definitions.**

*Definitions*. The following terms are defined for purposes of this subpart.

*Complete protection time (CPT)* means the time from application of a skin-applied insect repellent until efficacy failure, which is described in Product Performance Test Guideline 810.3700 – Insect Repellents to be Applied to Human Skin.

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

*Invasive species* means with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health. .

*Performance standard* means a benchmark or reference against which the efficacy of the pesticide is compared (including, but not limited to, the ability of the pesticide product to control, kill, or repel an invertebrate pest species).

*Pest group labeling claim* means a claim or statement on the labeling of the pesticide product that the product is effective against a group 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.

*Pest-specific labeling claim* means a claim or statement on the labeling of the pesticide product that the product is effective against a particular arthropod species, such as German cockroach or house fly.

*Pest sub-group labeling claim* means a claim or statement on the labeling of the pesticide product that the product is effective against 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 pest species, which may or may not have a proposed pest group.

*Skin-applied insect 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. Efficacy of skin-applied insect repellents is expressed as complete protection time.

*Species* means a group of organisms all of which have a high degree of physical and genetic similarity, generally interbreed only among themselves, and show persistent differences from members of allied groups of organisms.

*Wood-destroying* applies to pests that feed on or nest in 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 capable of transmitting the causative agent of human and/or animal disease, including but not limited to mosquitoes and ticks

**§ 158.1703 Application Categories.**

*Application Categories*. The following terms are defined for purposes of this subpart.

*Bait treatment* means a pesticide product intended to be ingested by the target pest that kills or controls an invertebrate pest such as ants, cockroaches, or termites. This is normally through the insect feeding on the product directly, but may also include products which the target will contact 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. pheromone) which is intended to attract the target pests over a greater distance.

*Soil-applied termiticides* means pesticide products that are applied to the soil beneath and/or 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 repellents* include treatments of both indoor and outdoor sites where the product is applied into the air rather than onto a surface or the skin in order to drive away insects or other arthropods from that space. They are intended to repel the target pest through the dispersal of pesticide into the atmosphere of a room or other open space.

*Structural protection* means the prevention of termite or other wood-destroying pest activity in an entire structure as the result of an application of a pesticide product.

**§ 158.1704 Performance standards for data acceptability.**

(a) *General*. The claim stated on the pesticide product labeling (such as knockdown, control, mortality, or repellency) determines the performance standard that must be met. In the absence of specific pest/labeling claims/performance standards specified in §§ 158.1708 through 158.1799, the performance standards of paragraphs (b) and (c) apply.

(b) *Skin-applied insect repellent labeling claims*. (1) For skin-applied insect repellent labeling claims, the performance standard must be greater than or equal to 2-hours complete protection time.

(2) Any testing required under 40 CFR part 158 which involves any human subjects must comply with all applicable requirements under 40 CFR part 26. For example, 40 CFR part 26 requirements are pertinent to the 40 CFR part 158 testing requirement if the testing involves intentional exposure of human subjects. Protocols for such testing must be submitted to EPA for review prior to study initiation. Those protocols determined by EPA to involve intentional exposure of human subjects also require review by EPA's Human Studies Review Board (HSRB)) prior to study initiation. If you are uncertain about the applicability of the 40 CFR part 26 requirements to this 40 CFR part 158 testing requirement or uncertain about the nature of your planned testing (such as, for example, whether the testing would involve intentional exposure of human subjects or whether the testing would be an observational study), you should contact the Agency prior to initiating the testing.

(c) *Labeling claims for products other than skin-applied insect repellents*. Unless otherwise specified in §§ 158.1710 through 158.1786, for pesticides other than skin-applied insect repellents, the performance standard for a product performance claim against a pest must be greater than or equal to 90 percent, except for non-wearable spatial repellents where the

performance standard is greater than or equal to 75 percent.

**§ 158.1705 Test Guidelines.**

EPA has published the Harmonized Test Guidelines, which set forth the recommended approach to generate the data required in this subpart. The Product Performance Guidelines (Series 810, Group C -- Invertebrate Control Agent Test Guidelines) are available on the Agency's website. These guidelines cover some, but not all, of the tests that would be used to generate data under this subpart. In instances where there is a conflict between one of the Harmonized Test Guidelines and the provisions of this subpart, this subpart will control.

**§ 158.1707 Data Requirement Modifications.**

The data requirements (including the performance standards associated with the data requirements) specified in this subpart as applicable to a category of products will not always be appropriate for every product in that category. Data requirements may, on a case-by-case basis, be adjusted by EPA in response to requests for novel technologies or products that have unusual physical, chemical, or biological properties or atypical use patterns which would make a particular data requirement, or data performance standard, inappropriate. Requests for such data requirement modifications must be submitted the same manner as waiver requests submitted under 40 CFR 158.45. EPA will respond in writing to those requests. The Agency may modify data requirements it finds are inappropriate for the pesticide in question, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

**§ 158.1708 Invasive species claims.**

(a) *General*. In addition to those species specified in paragraph (b) of this section, if an application for registration or amended registration requests a labeling claim for effectiveness

against an invasive invertebrate species, then on a case-by-case basis, EPA may require submission of product performance data and establish performance standards for those data to support those claims for effectiveness.

(b) *Specific*. Applications for registration or amended registration requests for a labeling claim for the emerald ash borer, *Agrilus planipennis*, or Asian longhorned beetle, *Anoplophora glabripennis*, must be accompanied by product performance data to support those claims for effectiveness.

**§ 158.1709 Invertebrate disease vector claims.**

If an application for registration or amended registration requests a labeling claim specific to a disease vector (such as repels mosquitoes that may carry West Nile virus), then submission of testing conducted with the species specific to the disease vector claim and subject to specific performance standards is required even if the test species is not specifically required in §§ 158.1712 through 158.1786.

**§ 158.1710 Structural and wood-destroying pest claims.**

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

**§ 158.1712 Mites (excluding Chiggers).**

(a) *General*. The tables and test notes in this section apply to dust, human itch or scabies, and dog follicle mites. The claim stated on the pesticide product labeling determines the required test species. The required test species for a specific type of mite claim appear in paragraph (b) of this section and the required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For pesticide products making a claim against mites, the required test species appear in the following table.

**Table 1 of 158.1712—Required Test Species for Products Making a Claim Against Mites (excluding Chiggers)**

| Labeling Claim | Required Test Species |
|---|---|
| Dog Follicle Mite | Dog follicle mite (*Demodex canis*) |
| Dust Mite | Testing on one of the following species is required:<br>American house dust mite (*Dermatophagoides farinae*)<br>OR<br>European house dust mite (*Dermatophagoides pteronyssinus*) |
| Human Itch or Scabies Mite | Human itch mite (*Sarcoptes scabiei*) |

(c) *Performance standards*. (1) For the dog follicle mite, a performance standard of 100 percent is required.

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

**§ 158.1714 Chiggers.**

If the pesticide product labeling makes a claim against chiggers, then testing is required using the following test species: Chigger (*Trombicula alfreddugesi*).

**§ 158.1718 Ticks.**

(a) *General*. The table and test notes in this section apply to hard ticks (including cattle ticks) and soft ticks. The claim stated on the pesticide product labeling determines the required test species. The required test species for a specific type of tick claim appear in paragraph (b) of this section. Specific parameters that apply to individual tests appear in paragraph (c) of this section. For a claim against any specific species of “ticks” that individual species and all the listed representative species for “ticks” must be tested, but not the representative species for cattle ticks or soft ticks. Claims against ticks in association with tick borne diseases are also subject to the requirements in § 158.1709.

(b) *Test species*. For pesticide products making a claim against ticks, the required test

species appear in the following table.

**Table 1 of 158.1718—Required Test Species for Products Making a Claim Against Ticks**

| Labeling Claim | Required Test Species |
|---|---|
| Ticks | Testing on a total of three hard tick species is required:<br>Blacklegged tick (*Ixodes scapularis*)<br>AND<br>Lone star tick (*Amblyomma americanum*)<br>AND<br>One of the following three species:<br>American dog tick (*Dermacentor variabilis*)<br>OR<br>Brown dog tick (*Rhipicephalus sanguineus*)<br>OR<br>Rocky Mountain wood tick (*Dermacentor andersoni*) |
| Cattle Ticks | Testing on one of the following species is required:<br>Southern cattle tick (*Rhipicephalus microplus*)<br>OR<br>Cattle fever tick (*Rhipicephalus annulatus*) |
| Soft Ticks | Soft tick (*Ornithodoros hermsi*) |

(c) *Specific parameters*. The following parameters are required.

1. For products applied to dogs, testing is required on three species: Blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), and Brown dog tick (*Rhipicephalus sanguineus*).

2. For products applied to cats, testing is required on three species: Blacklegged tick (*Ixodes scapularis*), Lone star tick (*Amblyomma americanum*), and American dog tick (*Dermacentor variabilis*).

**§ 158.1722 Scorpions.**

If the pesticide product labeling makes a claim against scorpions, then testing is required using the following test species: Striped bark scorpion (*Centruroides vittatus*).

**§ 158.1726 Spiders.**

(a) *General*. The table in this section applies to spiders. The product labeling claim determines the required test species. The required test species for spider labeling claims appear

in paragraph (b) of this section.

(b) *Test species*. For products making a claim against spiders, the test species for labeling claims appear in the following table.

**Table 1 of 158.1726—Required Test Species for Products Making a Claim Against Spiders**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| **Pest Group Claim** | |
| Spiders | Testing on two species is required:<br>Brown recluse spider (*Loxosceles reclusa*)<br>AND<br>One of the following species is required:<br>Northern black widow spider (*Latrodectus variolus*)<br>OR<br>Southern black widow spider (*Latrodectus mactans*)<br>OR<br>Western black widow spider (*Latrodectus hesperus*) |
| **Pest Sub-Group Claims** | |
| Black Widow Spiders | Testing on one of the following species is required:<br>Northern black widow spider (*Latrodectus variolus*)<br>OR<br>Southern black widow spider (*Latrodectus mactans*)<br>OR<br>Western black widow spider (*Latrodectus hesperus*) |
| **Pest-Specific Claims** | |
| Brown recluse spider | Brown recluse spider (*Loxosceles reclusa*) |
| Brown widow spider | Brown widow spider (*Latrodectus geometricus*) |
| Northern black widow spider | Northern black widow spider (*Latrodectus variolus*) |
| Southern black widow spider | Southern black widow spider (*Latrodectus mactans*) |
| Western black widow spider | Western black widow spider (*Latrodectus hesperus*) |

**§ 158.1732 Centipedes.**

(a) *General*. The table in this section applies to centipedes. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of the section.

(b) *Test species*. For products making a claim against centipedes, the required test species for a labeling claim is set forth in the following table.

**Table 1 of 158.1732—Required Test Species for Products Making a Claim Against Centipedes**

| Labeling Claim | Required Test Species |
|---|---|
| Centipedes | Testing on one of the following species is required:<br>House centipede (*Scutigera coleoptrata*)<br>OR<br>Florida blue centipede (*Hemiscolopendra marginata*)<br>OR<br>*Scolopendra* sp. |

**§ 158.1736 Lice.**

(a) *General*. The table in this section applies to human lice. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against lice, the required test species for a labeling claim appear in the following table.

**Table 1 of 158.1736—Required Test Species for Products Making a Claim Against Lice**

| Labeling Claim | Required Test Species |
|---|---|
| Lice | Testing on one of the following species is required:<br>Head louse (*Pediculus humanus capitis*)<br>OR<br>Body louse (*Pediculus humanus humanus*) |

(c) *Performance standards*. For labeling claims against lice, a performance standard of 100 percent is required.

**§ 158.1740 Fleas.**

(a) *General*. The table in this section applies to fleas. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against fleas, the required test species for a labeling claim is set forth in the following table.

**Table 1 of 158.1740—Required Test Species for Products Making a Claim Against Fleas**

| Labeling Claim | Required Test Species |
|---|---|
| **Pest Group Claim** | |
| Fleas | Testing on the following species is required:<br>Cat flea (*Ctenocephalides felis*) |
| **Pest-Specific Claims** | |
| Cat flea | Cat flea (*Ctenocephalides felis*) |
| Chigoe flea | Chigoe flea (*Tunga penetrans*) |
| Dog flea | Dog Flea (*Ctenocephalides canis*) |
| Hen flea | Hen flea (*Ceratophyllus gallinae*) |
| Human flea | Human flea (*Pulex irritans*) |
| Oriental rat flea | Oriental rat flea (*Xenopsylla cheopis*) |

**§ 158.1744 Cockroaches.**

(a) *General*. The table in this section applies to cockroaches. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. Specific parameters that apply to individual tests and labeling claims appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against cockroaches, the required test species for a labeling claim for cockroaches and the test species for pest-specific label claims appear in the following table.

**Table 1 of 158.1744—Required Test Species for Products Making a Claim Against Cockroaches**

| Labeling Claim | Required Test Species |
|---|---|
| **Pest Group Claims** | |
| Cockroaches | Testing on two species is required:<br>American cockroach (*Periplaneta americana*)<br>AND<br>German cockroach (*Blattella germanica*) |
| **Pest-Specific Claims** | |
| American cockroach | American cockroach (*Periplaneta americana*) |
| Australian cockroach | Australian cockroach (*Periplaneta australasiae*) |
| Brown cockroach | Brown cockroach (*Periplaneta brunnea*) |
| Brownbanded cockroach | Brownbanded cockroach (*Supella longipalpa*) |
| German cockroach | German cockroach (*Blattella germanica*) |
| Oriental cockroach | Oriental cockroach (*Blatta orientalis*) |
| Smokybrown cockroach | Smokybrown cockroach (*Periplaneta fuliginosa)* |
| Turkestan cockroach | Turkestan cockroach (*Blatta lateralis*) |

**§ 158.1748 Keds, Screwworms, and Bot Flies.**

(a) *General*. The table in this section applies to keds, screwworms, and bot flies. The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against keds, screwworms, and bot flies, the required test species for a labeling claim appear in the following table.

**Table 1 of 158.1748—Required Test Species for Products Making a Claim Against Keds, Screwworms, and Bot Flies**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| Bot Flies (excluding Human bot fly) | Testing is required on one of the following species:<br>Horse bot fly (*Gasterophilus intestinalis*)<br>OR<br>Throat bot fly (*Gasterophilus nasalis*)<br>OR<br>Nose bot fly (*Gasterophilus haemorrhoidalis*) |
| Human bot fly | Human bot fly (*Dermatobia hominis*) |
| Keds | Testing is required on the following species:<br>Sheep ked (*Melophagus ovinus*) |
| Screwworms | Testing is required on one of the following species:<br>Screwworm (*Cochliomyia hominivorax*)<br>OR<br>Secondary screwworm (*Cochliomyia macellaria*) |

**§ 158.1752 Filth Flies.**

(a) *General*. The table in this section applies to filth flies. The product labeling claim determines the required test species. The required test species for a labeling claim against filth flies or specific species of filth flies appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against filth flies, the required test species for a labeling claim against filth flies appear in the following tables.

**Table 1 of 158.1752—Required Test Species for Products Making a Claim Against Filth Flies**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| **Pest Group Claim** | |
| Filth Flies | Testing on two species is required: |

| | |
|---|---|
| | House fly (*Musca domestica*)<br>AND<br>One of the following species is required:<br>Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies)<br>OR<br>Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies) |
| **Pest-Specific Claims** | |
| Blow fly | Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies) |
| Cluster fly | Cluster fly (*Pollenia rudis*) |
| Face fly | Face fly (*Musca autumnalis*) |
| Flesh fly | Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies) |
| House fly | House fly (*Musca domestica*) |
| Little house fly | Little house fly (*Fannia canicularis*) |

**§ 158.1756 Mosquitoes.**

(a) *General*. The tables and test notes in this section apply to mosquitoes. The required test species for a labeling claim against mosquitoes appears in paragraph (b) of this section. For a claim against any specific species of mosquito, that individual species and all the required test genera must be tested. Claims against mosquitos in association with mosquito-borne diseases are also subject to the requirements in § 158.1709.

(b) *Test species*. For products making a claim against mosquitoes, the required test species for a labeling claim is set forth in the following table.

**Table 1 of 158.1756—Required Test Species for Products Making a Claim Against Mosquitoes**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| Mosquitoes | Testing in three genera (*Culex*, *Aedes*, and *Anopheles*) of mosquitoes is required.<br>One of the following *Culex* species:<br>*Culex pipiens*<br>OR<br>*Culex quinquefasciatus*<br>OR<br>*Culex tarsalis*<br>AND one of the following *Aedes* species:<br>*Aedes aegypti* |

| | |
|---|---|
| | OR<br>*Aedes albopictus*<br>AND one of the following *Anopheles* species:<br>*Anopheles albimanus*<br>OR<br>*Anopheles freeborni*<br>OR<br>*Anopheles gambiae*<br>OR<br>*Anopheles punctipennis*<br>OR<br>*Anopheles quadrimaculatus*<br>OR<br>*Anopheles stephensi* |

**§ 158.1760 Biting Flies.**

(a) *General*. The tables in this section apply to biting flies, which includes biting midges and black flies. The product labeling claim determines the required test species. The required test species for biting fly labeling claims and the test species for pest-specific labeling claims appear in paragraphs (b) of this section.

(b) *Test species*. For products making a claim against biting flies, the required test species for a labeling claim and the test species for pest-specific label claims appear in the following table.

**Table 1 of 158.1760—Required Test Species for Products Making a Claim Against Biting Flies**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| **Pest Group Claim** | |
| Biting flies (excluding Sand flies) | Testing is required on three species:<br>Stable fly (*Stomoxys calcitrans*)<br>AND<br>one of the large biting fly species:<br>Black horse fly (*Tabanus atratus*)<br>OR<br>Deer fly (*Chrysops* sp.)<br>OR<br>Striped horse fly (*Tabanus lineola*)<br>AND one of the small biting fly species:<br>Biting midge (punkie, granny nipper, no-see-um) (any |

| | |
|---|---|
| | *Culicoides* sp.)<br>OR<br>Black fly (any *Simulium* sp. or *Prosimulium* sp.)<br>OR<br>Black gnat (any *Leptoconops* sp.) |
| **Pest Sub-Group Claims** | |
| Large Biting Flies | Testing is required on two species:<br>Stable fly (*Stomoxys calcitrans*)<br>AND one of the following species:<br>Black horse fly (*Tabanus atratus*)<br>OR<br>Deer fly (*Chrysops* sp.)<br>OR<br>Striped horse fly (*Tabanus lineola*) |
| Small Biting Flies (excluding Sand flies) | Testing is required on one of the following species:<br>Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.)<br>OR<br>Black fly (*Simulium* sp. OR *Prosimulium* sp.)<br>OR<br>Black gnat (*Leptoconops* sp.) |
| **Pest-Specific Claims** | |
| Biting midges (punkie, granny nipper, no-see-um) | Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.) |
| Black flies | Testing on one of the following species is required:<br>*Simulium* sp.<br>OR<br>*Prosimulium* sp. |
| Black gnats | Black gnat (*Leptoconops* sp.) |
| Deer flies | Deer fly (*Chrysops* sp.) |
| Greenhead | Greenhead (*Tabanus nigrovittatus*) |
| Horn fly | Horn fly (*Haematobia irritans*) |
| Horse flies | Testing on one of the following species is required:<br>Black horse fly (*Tabanus atratus*),<br>OR<br>Striped horse fly (*Tabanus lineola*) |
| Sand flies | Testing on one of the following species is required:<br>*Lutzomyia* sp.<br>OR<br>*Phlebotomus* sp. |
| Stable fly | Stable fly (*Stomoxys calcitrans*) |

**§ 158.1768 Bed Bugs.**

(a) *General*. The table in this section applies to bed bugs. The product labeling claim

determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against bed bugs, the required test species for a labeling claim appear in the following table.

**Table 1 of 158.1768—Required Test Species for Products Making a Claim Against Bed Bugs**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| **Pest Group Claim** | |
| Bed bugs | Common bed bug (*Cimex lectularius*) |
| **Pest-Specific Claims** | |
| Common bed bug | Common bed bug (*Cimex lectularius*) |
| Tropical bed bug | Tropical bed bug (*Cimex hemipterus*) |

**§ 158.1772 Conenose Bugs and Kissing Bugs.**

(a) *General*. The table in this section applies to Conenose bugs and Kissing bugs. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against either the conenose and/or kissing bugs, the required test species for a labeling claim is set forth in the following table.

**Table 1 of 158.1772—Required Test Species for Products Making a Claim Conenose and Kissing Bugs**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| Conenose bug | Conenose bug (*Triatoma sanguisuga*) |
| Kissing bug | Kissing bug (*Triatoma protracta*) |

**§ 158.1776 Ants (excluding carpenter ants).**

(a) *General*. The table in this section applies to ants (excluding carpenter ants). The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against ants (excluding carpenter ants), the required test species for a labeling claim appear in the following table, unless otherwise specified

in paragraphs (c) or (d).

**Table 1 of 158.1776—Required Test Species for Products Making a Claim Against Ants (excluding carpenter ants)**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| **Pest Group Claim** | |
| Ants (excluding carpenter ants) | Testing is required on the following two species:<br>Pharaoh ant (*Monomorium pharaonis*)<br>AND<br>Red imported fire ant (*Solenopsis invicta*) |
| **Pest Sub-Group Claim** | |
| Fire and Harvester | Testing is required on the following species:<br>Red imported fire ant (*Solenopsis invicta*) |
| Fire ants | Testing is required on the following species:<br>Red imported fire ant (*Solenopsis invicta*) |
| **Pest-Specific Claims** | |
| European fire ant | European fire ant (*Myrmica rubra*) |
| Harvester ant | Harvester ant (*Pogonomyrmex* sp.) |
| Pharaoh ant | Pharaoh ant (*Monomorium pharaonis*) |
| Red imported fire ant | Red imported fire ant (*Solenopsis invicta*) |
| Southern fire ant | Southern fire ant (*Solenopsis xyloni*) |
| Tropical fire ant | Tropical fire ant (*Solenopsis geminata*) |
| Black imported fire ant | Black imported fire ant (*Solenopsis richteri*) |

(c) *Colony Claims*. For colony claims, testing must be done specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on, *S. invicta*, *S. richteri*, or their hybrid.

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

**§ 158.1780 Bees, Wasps, Yellowjackets, and Hornets.**

(a) *General*. The table in this section applies to bees, wasps, yellowjackets, and hornets. The labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against bees, wasps, yellowjackets, and hornets, the required test species for a labeling claim appear in the following table, unless otherwise specified in paragraph (c).

**Table 1 of 158.1780—Required Test Species for Products Making a Claim Against Bees, Wasps, Yellowjackets, and Hornets**

| **Labeling Claim** | **Required Test Species** |
|---|---|
| **Pest Group Claims** | |
| Bees, Wasps, Yellowjackets, and Hornets | Testing on three species is required:<br>Two Yellowjacket species (one *Vespula* sp. AND the Bald-faced hornet (*Dolichovespula maculata*))<br>AND<br>one Paper wasp (*Polistes* sp.) |
| **Pest-Specific Claims** | |
| Bald-faced hornet | Bald-faced hornet (*Dolichovespula maculata*) |
| Mud dauber wasp | Mud dauber wasp (*Sphecidae* sp.) |
| Paper wasp | Paper wasp (*Polistes* sp.) |
| Yellowjackets | Yellowjacket (*Vespula* sp.) |

c) *Colony Claims*. For colony claims, except *Vespula* spp., testing must be specific to the species listed. Acceptable data for any *Vespula* species may support a yellowjacket colony claim for ground nesting *Vespula* species; however, species-specific claims need to be supported by data from testing of the specific species. Colony claims against *Vespula* spp. have a performance standard of 100%.

**§ 158.1782 Carpenter Ants.**

(a) *General*. The table in this section applies to carpenter ants. The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against carpenter ants, the required test species for a labeling claim appear in the following table.

**Table 1 of 158.1782—Required Test Species for Products Making a Claim Against Carpenter Ants**

| Labeling Claim | Required Test Species |
|---|---|
| Carpenter ants | Testing on one of the following carpenter ant species is required:<br>Black carpenter ant (*Camponotus pennsylvanicus*)<br>OR<br>Florida carpenter ant (*Camponotus floridanus*)<br>OR<br>Western carpenter ant (*Camponotus modoc*) |

(c) *Performance standards*. The performance standards for pesticide products making certain claims against carpenter ants appear in the following table. The performance standards for labeling claims that are not specifically provided in the following table appear in § 158.1704.

**Table 2 of 158.1782—Performance Standards for Certain Claims Against Carpenter Ants**

| Application Category | Performance Standard |
|---|---|
| Bait Treatment | 95% prevention of damage to wood for ≥ 3 years |
| Non-Structural: Wood Preservative Treatment | 100% prevention of damage to wood for ≥ 2 years |
| Structural Protection | 95% prevention of damage to wood ≥ 5 years |

**§ 158.1784 Wood-destroying beetles.**

(a) *General*. The tables and test notes in this section apply to wood-destroying beetles. The labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against wood-destroying beetles, the required test species for a labeling claim is set forth in the following table.

**Table 1 of 158.1784—Required Test Species for Products Making a Claim Against Wood-Destroying Beetles**

| Labeling Claim | Required Test Species |
|---|---|
| True powderpost beetles | Testing on one species from the Lyctinae subfamily is required. |

| | |
|---|---|
| Wood-destroying or wood-boring beetles | Testing on three species is required:<br>Anobiid beetle (*Anobiidae* sp.)<br>AND<br>Bostrichid beetle (*Bostrichidae* sp.)<br>AND<br>Old house borer (*Hylotrupes bajulus*) |

(c) *Performance standards*. The performance standards for pesticide products making certain claims against wood-destroying beetles appear in the following table. The performance standards for labeling claims that are not specifically provided in the following table appear in § 158.1704.

**Table 2 of 158.1784—Performance Standards for Certain Claims against Wood-Destroying Beetles**

| Application Category | Performance Standard |
|---|---|
| Bait Treatment | 95% prevention of damage to wood ≥ 3 years |
| Non-Structural: Wood Preservative Treatment | 100% prevention of damage to wood for ≥ 2 years |
| Structural Protection | 95% prevention of damage to wood ≥ 5 years |

**§ 158.1786 Termites.**

(a) *General*. The tables and test notes in this section apply to the subterranean termite, desert subterranean termite, Formosan subterranean termite, drywood termite, and dampwood termite. The labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against termites, the required test species for a labeling claim appear in the following table.

**Table 1 of 158.1786—Required Test Species for Products Making a Claim Against Termites**

| Labeling Claim | Required Test Species |
|---|---|
| **Pest Group Claim** | |
| Termites | Testing on species from four genera of termites is required:<br>Testing is required on the following *Coptotermes* termite:<br>*Coptotermes formosanus* |

| | |
|---|---|
| | AND one of the following *Reticulitermes* species:<br>*Reticulitermes flavipes*<br>OR<br>*Reticulitermes hesperus*<br>OR<br>*Reticulitermes virginicus*<br>AND one of the following arboreal termite species:<br>*Nasutitermes coringer* (Motschulsky)<br>AND one of the following drywood termite species:<br>*Cryptotermes brevis*<br>OR<br>*Cryptotermes cavifrons*<br>OR<br>*Incisitermes minor*<br>OR<br>*Incisitermes snyderi* |
| **Pest Sub-Group Claim** | |
| Arboreal Termites | Testing of one arboreal termite species is required:<br>*Nasutitermes coringer* (Motschulsky) |
| Dampwood Termites | Testing of the following dampwood termite is required:<br>*Zootermopsis* sp. |
| Drywood Termites | Testing of one of the following drywood termites is required:<br>*Cryptotermes brevis*<br>OR<br>*Cryptotermes cavifrons*<br>OR<br>*Incisitermes minor*<br>OR<br>*Incisitermes snyderi* |
| Subterranean Termites, including Formosan Subterranean Termites | Testing in two genera of termites is required: Testing on the following *Coptotermes* species is required:<br>*Coptotermes formosanus*<br>AND one of the following *Reticulitermes* species:<br>*Reticulitermes flavipes*<br>OR<br>*Reticulitermes hesperus*<br>OR<br>*Reticulitermes virginicus* |

(c) *Performance standards*. The performance standards for pesticide products making certain claims against termites appear in the following table. The performance standards for labeling claims not provided in the following table appear in § 158.1704.

**Table 2 of 158.1786—Performance Standards for Certain Claims Against Termites**

| **Application Category** | **Performance Standard** |
|---|---|
| Bait Treatment | 95% prevention of damage to wood ≥3 years |
| Non-Structural: Wood Preservative Treatment | 100% Prevention of damage to wood for ≥ 2 years |
| Structural Protection | 95% prevention of damage to wood ≥ 5 years |

5. Revise § 158.2070 in subpart U to read as follows:

**§ 158.2070 Biochemical Pesticides Product Performance Data Requirements.**

(a) *General*. Product performance data must be developed for all biochemical pesticides. Each applicant must ensure through testing that the product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(b) *Product performance data for each product that bears a claim against an invertebrate pest that is covered by subpart R of this Part*. The product performance data requirements of subpart R of this part apply to biochemical products covered by this subpart. Product performance data must be submitted with any application for registration or amended registration. The performance standards required in subpart R of this part also apply to biochemical pesticide products. However, data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case basis pursuant to the waiver provisions in 40 CFR 158.45 and the provisions in 40 CFR 158.1707.

(c) *Product performance data for each product that bears a public health claim, excluding those covered under paragraph (b)*. Product performance data must be submitted with any application for registration or amended registration, if the product bears a claim to control public health pests, such as pest microorganisms infectious to humans in any area of the inanimate environment, or a claim to control vertebrates, including but not limited to, rodents,

birds, bats, canids, and skunks.

6. Revise § 158.2160 in subpart V to read as follows:

**§ 158.2160 Microbial Pesticides Product Performance Data Requirements.**

(a) *General*. Product performance data must be developed for all microbial pesticides. Each applicant must ensure through testing that the product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(b) *Product performance data for each product that bears a claim against an invertebrate pest that is covered by subpart R of this part*. The product performance data requirements of subpart R of this part apply to microbial products covered by this subpart. Product performance data must be submitted with any application for registration or amended registration. However, data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case basis pursuant to the waiver provisions in 40 CFR 158.45 and the provisions in 40 CFR 158.1707.

(c) *Product performance data for each product that bears a public health claim, excluding those covered under paragraph (b)*. Product performance data must be submitted with any application for registration or amended registration, if the product bears a claim to control public health pests, such as pest microorganisms infectious to humans in any area of the inanimate environment, or a claim to control vertebrates, including but not limited to, rodents, birds, bats, canids, and skunks.

7. In § 158.2200, revise paragraph (b) in subpart W to read as follows:

**§ 158.2200 Applicability.**

***  *  *  *  ***

(b) *A product that bears both antimicrobial and non-antimicrobial uses or claims*. Such a product is subject to the data requirements for pesticides in subparts C through O, R, and U or V of this part with respect to its non-antimicrobial uses and claims, and to the requirements of this subpart with respect to its antimicrobial uses and claims.

*  *  *  *  *