Dated: April 11, 2022.

Meghan A. McCollister,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Q—Iowa

■ 2. In § 52.820, the table in paragraph (e) is amended by adding the entry ''(55)'' in numerical order to read as follows:

§ 52.820 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED IOWA NONREGULATORY PROVISIONS

Name of non regulatory SIP provision	Applicable geographic or non-attainment area	State submittal date	EPA approval date	Explanation
*	* *	*	* *	* *
(55) Transport SIP for the 2015 Ozone Standard.	Statewide	11/30/2018	April 15, 2022, [insert **Federal Register** citation].	[EPA–R07–OAR–2021–0870; EPA–HQ–OAR–2021–0663; FRL–9468–02–R7]. This transport SIP shows that Iowa does not significantly contribute to ozone nonattainment or maintenance in any other state. This submittal is approved as meeting the requirements of Clean Air Act section 110(a)(2)(D)(i)(I).

[FR Doc. 2022–08028 Filed 4–14–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA–HQ–OPP–2020–0124; FRL–5331–05–OCSPP]

RIN 2070–AJ49

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is codifying 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: This final rule is effective on June 14, 2022.

ADDRESSES: The EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2020–0124. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Sara Kemme, Mission Support Division (7101M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1217; email address: *kemme.sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You 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 codifying 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 will inform the data needed to substantiate pesticidal claim(s) made on the label of the pesticide products. The 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 codifying 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 final 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. Applicants must submit studies demonstrating their product's efficacy using specified test species and meeting specified performance standards. Numerical performance standards, such as the percent mortality, percent repellency, percent knockdown, or complete protection time, will need to be achieved to deem the data acceptable for the purpose of supporting a product making a claim against an invertebrate pest. Codifying essential elements relating to test species and performance standards will provide the regulated community a better understanding of the data necessary to support registration of a product that claims efficacy against invertebrate pests.

This final rule:

- Codifies a new subpart R in 40 CFR part 158 entitled, ''Product Performance for Products Claiming Effectiveness Against Invertebrate Pests;''
- Renames 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 new subpart R; and
- Revises 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, this final rule updates 40 CFR 158.1(c) to insert references to the subparts to categorize them under the ''scope of the subparts'' section. EPA is also updating subpart W at 40 CFR 158.2200(b) to insert a cross reference to the newly created 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, for certain pesticides intended for preventing, destroying, repelling, or mitigating specified invertebrate pest of significant public health or economic importance.

This final 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 final rule covers some invertebrate pests in addition to those specified in PRIA 4 due to their public health, economic, or ecological significance (*e.g.,* wood destroying insects).

D. Why is EPA taking this action?

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

1. *Obtaining reliable data to make the statutory finding.* The data submitted to EPA for review and evaluation as a result of this final rule 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.* This final rule identifies the specific data requirements that apply to pesticides making claims against certain categories of invertebrate pests. As with the original design of 40 CFR part 158 in 1984, and continued in 2007, given the variations in pesticide chemistry, exposure, and hazard, this final rule 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 rulemaking, EPA prepared an economic analysis entitled, ''Cost Analysis of the Final Product Performance Rule'' (Ref. 1) which presents an economic 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 finalized 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 or ecological 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. This final rule codifies 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 covered pests.

This final rule clarifies data requirements and therefore improves efficiency and effective use of resources by both the Agency and industry. Moreover, this final rule will serve the public by ensuring that appropriate efficacy data are available to substantiate the label claims on these products. 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 final rule will 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 158.30, 158.45 and 40 CFR 158.1707, on a case-by-case basis the Agency may consider alternative information and data that are more appropriate than the final rule requirements, considering the intended purpose and pesticidal claims of a pesticidal product.

EPA estimates that this final rule will 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 final 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. 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—SUMMARY OF BENEFITS AND COSTS OF THE FINAL RULE

Expected Benefits of the Final 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. • 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. • *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 Final Rule	
No increased risk to human health or the environment is expected from publication of the final rule. No increased costs to registrants or consumers are expected from publication of the final rule. Expected direction of costs for the Agency from the final rule is unknown.	
Other Impacts	
Small Business Impacts	• No significant impact on a substantial number of small entities. • Affected NAICS codes contain up to 5,438 small entities. 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.

II. Background

The proposed rule (86 FR 15362, March 22, 2021) (FRL–10011–06) provided detailed background information on the pesticide registration process, the preexisting regulatory framework, why product performance data matter, and the relationship between this rulemaking and other guidance documents (see proposed rule pages 15365–15368). This section briefly summarizes that information.

A. Statutory Background

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.'' This final rule identifies the data requirements EPA has determined are typically necessary to determine whether the proposed claims of efficacy are warranted, along with the opportunity for waiver or modifications pursuant to 40 CFR 158.30 and 158.45 and newly codified 40 CFR 158.1707.

B. Registration Regulatory Framework

FIFRA section 3 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).

The pre-existing regulatory data requirements for product performance for pesticides are contained in 40 CFR part 158, subpart E, which for the most part is specific to vertebrates (*e.g.,* birds, rodents, etc.); 40 CFR part 158, subpart U, section 158.2070, which is specific to biochemicals; 40 CFR, subpart V section 158.2160, which is specific to microbials; and 40 CFR part 158, subpart W, 158.2220, which is specific to 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. This rulemaking creates a new subpart R for invertebrate product performance requirements to capture the updates to the product performance data requirements for pesticides, and makes conforming edits to subparts E, U, V, and W.

C. Why does product performance matter?

The primary goal of this final rule 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. 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, (Refs. 2 and 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 or economic importance. The preamble to the proposed rule provides a more detailed discussion of the consequence of ineffective control of these pests (see proposed rule at page 15366).

D. 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 EPA's product 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.

E. EPA's Harmonized Test Guidelines for Invertebrate Product Performance

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.

As a general matter, this final regulation describes the product performance data requirements, and the guidelines give examples of how to conduct studies to generate those data. 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.

III. The Scope of Subpart R

The proposed rule provided a detailed discussion of EPA's rationale for the scope of the rule, including EPA's reasoning for including the specified pests, EPA's methods for selecting the representative test species, and the reasoning behind the performance standards. (See proposed rule at pg. 15386). This section provides a summary of that discussion. Unit VII. of the preamble to this final rule discusses public comments related to the scope of the final rule and EPA's response to those comments. EPA selected three pest categories for this rule: Pests of significant public health importance, wood-destroying insects, and invasive species. The rationale for selection of these three categories follows.

A. Categories of Pests Covered by This Regulation

The invertebrate species of significant public health importance identified in this rule as requiring submission of product performance data are derived from the invertebrate pest list identified in PR Notice 2002–1, a draft update which was released for comment in 2020 (Ref. 2). These invertebrate pests pose a threat of injury, disease transmission and/or pathogen transfer, and allergen production. They can have venomous bites or stings, and can vector serious diseases such as Rocky Mountain Spotted Fever, Lyme Disease, Ehrlichiosis, West Nile Virus, Dengue Fever, Malaria, Encephalitis, Yellow Fever, Chikungunya Fever, and Zika Virus.

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. Similarly, invertebrate invasive species can impose serious economic costs by causing or vectoring diseases against native species that have little or no natural defenses. 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.

As proposed, EPA is not codifying a comprehensive list of all the specific invasive species for which product performance data might be deemed necessary. Currently, EPA is codifying product performance data submission requirements only for the emerald ash borer and the Asian longhorned beetle. However, 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.

B. 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. 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 a claim against the general group or subgroup. 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.

To develop the 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.

C. General Requirements

The provisions at 40 CFR 158.1700 contain the general requirements that are applicable to any pesticide product that is making a claim(s) against an invertebrate pest, and describes how to use the data tables in 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.

In order to ensure consistent implementation of subpart R, EPA is finalizing definitions specific to the subpart. The provisions at 40 CFR 158.1701 and 158.1703 contain the definitions pertaining to subpart R. The provisions at 40 CFR 158.1704 codify 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. The provisions at 40 CFR 158.1705 codify a reference to EPA's Harmonized Test Guidelines, which set forth a recommended approach to generate the data required for product performance testing. The provisions at 40 CFR 158.1707 state that on a case-by-case basis, the data requirements identified in subpart R may need to be modified 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. Pursuant to 40 CFR 158.30 and 158.45, EPA has historically taken the position that data requirements can be modified or waived on a case-by-case basis. The provision at 40 CFR 158.1707 is not intended to supersede or alter those provisions, but rather to provide that the data requirements, including the performance standards, in subpart R may be modified using the procedures consistent with those in 40 CFR 158.45. The provisions at 40 CFR 158.1709, state 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.

The provisions at 40 CFR 158.1710 state 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.

D. Pest-Specific Claims

EPA is codifying product performance data submission requirements for pest groups, sub-groups, and some specific species. 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. 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. For pests that are not listed as a ''pest-specific claim'' in subpart R, the data required to support a group (or subgroup) claim would also be sufficient to support pest-specific claims for species within that group. Consistent with EPA's current practices, EPA has added a provision at 40 CFR 158.1700(4)(b) that makes clear that for a pest-specific claim against any pest that is listed as a representative test species for a group or subgroup claim, pest-specific data would need to be submitted even if the pest is not listed in a subpart R provision explicitly requiring a pest-specific claim. For example, the American house dust mite (*Dermatophagoides farinae*) is listed as an option for testing for a claim against dust mites, and accordingly submission of data on the American house dust mite (*Dermatophagoides farinae*) would be needed for a pest-specific claim against American house dust mite (*Dermatophagoides farinae*). In contrast, the pavement ant (*Tetramorium caespitum*), for example, is not listed as a pest-specific claim nor is it a representative test species for a group or subgroup claim, thus it does not require submission of pest-specific data.

As noted in the preamble to the proposed rule, the provisions at 40 CFR 158.75 and 40 CFR 158.1708 would 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. Additionally, as proposed, EPA is finalizing provisions that would require group testing for mosquitos and ticks in order to make a claim against pests within those groups.

E. Data Requirements for Subpart R

The data requirements that EPA is finalizing 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. The product performance data needs being finalized in this rule 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, as explained elsewhere, are waivable under 40 CFR 158.45.

IV. Response to Public Comments

The 60-day public comment for the proposed rule closed on May 22, 2021. EPA received 16 unique submissions to the docket. Commenters included trade associations (5), industry groups (4), consulting groups (2), state government associations (1), public interest groups (1), and private citizens (3). In this unit, EPA provides a summary of the major issues raised by commenters and EPA's responses, as well as summaries of public comments that prompted changes to the proposed requirements for the final rule. All public comments and EPA's responses to comments received, including those that do not raise significant issues or substantially change the proposed requirements, are included in Response to Comments document (Ref. 4) that is available in the docket for this rule.

Commenters were supportive of the rulemaking. Their concerns were, in large part, focused and technical (*e.g.,* add XXX pest, change XXX performance standard and/or related to uncertainty around rule implementation). EPA also received several comments that are outside the scope of the rule (*e.g.,* related to testing guidelines). While EPA is finalizing this rule substantially as proposed, EPA is making some discrete changes to the rule in response to public comments. Those changes, and the reasons behind them, are discussed further in this Unit and in the Response to Comments Document.

A. Technical Comments

EPA received several technical comments on the proposed regulation, including suggestions to add categories of claims, add or remove representative tests species, add additional definitions, and reevaluate the listed performance standards.

One commenter suggested that EPA add a ''general flies'' claim to the regulations and that testing house fly, a *tabanid sp.,* blow fly sp., and *Fannia sp.* would warrant this claim. After review of this comment EPA has determined that it is appropriate to add a general fly label claim category to the regulatory provisions. However, Tabanids have been included and little house flies have been excluded because of their relative size. Therefore, a general flies label claim would require testing of the following five species: (1) House fly (*Musca domestica*), AND (2) (Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other genera of flesh flies) OR Blow fly (*Phaenicia* sp., *Calliphora* sp., and other genera of blow flies)), AND (3) Stable fly (*Stomoxys calcitrans*), AND (4) (Biting midge (punkie, granny nipper, no-see-um) (any *Culicoides* sp.) OR Black fly (any Simulium sp. or Prosimulium sp.) OR Black gnat (any *Leptoconops* sp.)), AND (5) (Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*)). For readability, EPA is combining the sections on ''Filth flies'' and ''Biting flies'' into one section for ''Flies.''

A commenter suggested adding an option to test the Arizona bark scorpion (*Centrurioides sculpturatus*) as an alternative to *Centruroides vittatus.* After review of the comment's suggestion, EPA agrees that the Arizona bark scorpion is more venomous and thus a greater health concern. EPA also agrees that it is a suitable alternative for testing for a claim against scorpions. Another comment recommended that EPA list *Anopheles hermsi* as a test species, because it is a closely related sibling species of *Anopheles freeborni.* EPA agrees with the commenter and is adding *Anopheles hermsi* as a testing option for the *Anopheles* genus. Accordingly, another scorpion (*Centrurioides sculpturatus*) and mosquito species (*Anopheles hermsi*) were added to the list of representative species options in 40 CFR 158.1722 and 40 CFR 158. 1756.

EPA received other comments suggesting changes to the representative test species, including requiring testing for only conenose or kissing bugs to receive a claim for both, allowing either the tropical or common bed bug as representatives for a general bed bug claim, substituting any recluse or widow spider as a representative species, adding *Aedes taeniorhynchus* as an additional option for testing the *Aedes* genus, including the lesser house fly as a representative species, and providing that Formosan subterranean termites are adequate for the entire group of ''subterranean termites. EPA is not adopting these suggestions because the Agency has determined that they do not provide adequate representation to support the claim or because the Agency does not have data to establish that they are adequate representatives. Please see the Response to Comments Document for more information on EPA's rationale for declining to adopt these suggestions.

Commenters requested that EPA confirm that for products wishing to claim efficacy against a single species of termite, testing on that species alone would be adequate. EPA proposed provisions for mosquitoes and ticks that specifically required group testing for an

individual species claim because they are high stakes disease vectors and because consumers have difficulty differentiating between species. This has also been the Agency's general practice for termiticides because, due to the cryptic nature of subterranean termites, it is not possible for an applicator to know which species are present at the site of application. Visual confirmation of only one genus or species does not negate the possibility of the presence of another species at the time of application or during the period over which the treatment is intended to provide protection. For subterranean termites, EPA did not propose regulatory text provisions analogous to those propose for mosquitoes and ticks because EPA does not generally receive requests for claims against a single species of subterranean termite and because EPA would intend to continue its current practice even absent the regulatory change in those rare cases a request for such claims is submitted.

In response to the comment submitted, however, EPA realizes that clear text in the provisions for ticks and mosquitoes may create confusion as to the data need in this context. As discussed in more detail in the Response to Comments document, no data have been provided to support the claim that *Coptotermes formosanus* is a more robust species and that products and application concentrations that are efficacious against *C. formosanus* are universally efficacious against the other subterranean termite species in the United States. (Refs. 5 & 6). As a result, EPA has generally concluded that products claiming efficacy against subterranean termites must demonstrate efficacy against both genera and EPA has generally required—for structural protection and wood preservative claims against subterranean termites—field testing in areas of the U.S. that have both *Reticulitermes* and *Coptotermes* species. (See, *e.g.,* the guidance provided in OPPTS Guideline 810.3800 (Ref. 7); see also Ref. 8). For this reason, in response to comment, EPA has added a provision to the final regulatory text specifying that for the structural protection and wood preservative claim categories, a claim against any specific genus of subterranean termite must be supported by data on that individual genus and all the required test genera for a subterranean termite claim must be tested and submitted.

A commenter raised concerns with the proposed terminology. The commenter suggested that ''Nonstructural: Wood Preservative Treatment'' be deleted and replaced with ''No Structural Protection'' and the definition of ''No Structural Protection'' be added to 158.1701. The terms ''Structural'' and ''non-structural'' are used in other facets of construction and should not be used as it will cause confusion. The commenter also suggested that in Table 2 to Paragraph (c) in sections 158.1782, 158.1784 and 158.1786, the column heading ''Application Category'' be changed to ''Label Claim'' as the criteria in each table are really related to claims.

In response to the concerns that the commenter raised, in addition to the definition of ''structural protection'' which was included in the proposal, EPA is adding a definition for ''wood protectants and other non-structural protection'' in § 158.1703, Application categories. With respect to the comment that in Table 2 to Paragraph (c) in sections 158.1782, 158.1784 and 158.1786, EPA should change the column heading ''Application Category'' to ''Label Claim,'' EPA is changing the column heading to ''Claim Category'' and reorganizing the table to clearly identify non-structural wood-preservative claims and structural protection claims. EPA chose ''Claim Category'' instead of the commenter's suggestion of ''Label Claim'' because a bait treatment is an application method not a label claim.

One commenter noted that EPA agreed with the SAP's conclusion that an across-the-board 95 percent standard was impractical, and EPA generally adjusted that standard to 90 percent, but kept the 95 and 100 percent performance standards for certain pests, including carpenter ants, termites, wood-destroying beetles, human mites and lice, wood-destroying pests, and non-structural wood preservative treatments. Commenters recommended lowering the standard to no higher than 90 percent for all covered pests because the commenters believe biological variability, scientific probabilities, and testing artifacts can affect the outcome of a study, and it is still difficult or impossible to rely on a performance standard greater than 90 percent. One commenter believes that a higher standard could impede the development of new chemistries.

As the commenter recognizes, for the majority of pests, EPA proposed and is finalizing in this rule a performance standard of 90 percent. However, for the limited instances where EPA proposed and is finalizing in this rule a performance standard above 90 percent, there are countervailing reasons why the lower standard is not appropriate. In those cases, EPA has determined that proposed performance standards are both attainable and prudent. Registrants can and have been meeting these standards for years. The studies are conducted under highly controlled field and/or laboratory conditions. EPA notes that the 100 percent performance standard for the dog follicle mite is to ensure a product works and should not require repeat treatment. Because dogs that show symptoms have a weakened immune system and would continue to show symptoms if the mites are not eliminated from the animal, the 100 percent standard is appropriate for efficacy against this pest. Additionally, for products that are intended to provide structural protection of homes and other occupied structures or prevention of damage to wood that is a critical element of a structure (*e.g.,* bridges), reducing the performance level could result in dangerous or financially ruinous damage. In the case of lice, complete eradication of the infestation is necessary to prevent reinfestation of the host by remaining insects.

With respect to the concern that performance standards of greater than 90 percent limit the development of novel products, EPA notes that provisions in the regulations give the Agency the flexibility to modify the data requirements, where appropriate (see 40 CFR 158.1707). Pursuant to that provision, data requirements may, on a case-by-case basis, be modified by EPA in response to written 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. The procedures for requesting a modification under 40 CFR 158.1707 are the same as the procedures for requesting a waiver under 40 CFR 158.45.

One commenter wrote that in section 158.1786 ''Termites'' table 2 the 95% claim being would be difficult to obtain, and the commenter questioned whether the table implies wood consumption would be the only measurement for termite trial performance standard. There are several types of termite trials such as direct mortality of individuals and structural protection field trials that typically use other performance standards. In response EPA wishes to clarify that the percentage damage to wood (*i.e.,* consumption of wood) is the endpoint in Table 2, as measured across all replicates, not within each replicate. Structural protection claims do not have direct mortality endpoints. Direct mortality endpoints would be appropriate for products that are intended to kill termites at the time of

application, but do not provide structural protection.

EPA also adjusted the final regulatory text for clarity and to correct omissions. The proposed regulatory text for 40 CFR 158.1780 singled out colony claims for *Vespula* spp. as having a 100% performance standard. In this final rule, EPA is clarifying that the 100% performance standard for colony claims applies to 40 CFR 158.1780 (bees, wasps, yellowjackets, and hornets) and that the reference to *Vespula* spp. was intended to be an example. Additionally, EPA has added provisions for colony claims and for claims for baits products and products involving outdoor use to the Carpenter Ants section (40 CFR 158.1782). In the proposal those provisions were included only in the Ants section (40 CFR 158.1776), but they are also applicable to carpenter ants. These changes are consistent with EPA's current practices and data needs.

B. Comments on the Implementation of the Rule

EPA received several comments and questions regarding how the Agency intends to implement the regulations. These comments included suggestions for a more defined process for covering invasive exotic species, questions about waivers or modifications of these data requirements, and questions about the status of existing pesticide products.

A commenter requested a transparent process for the addition of invasive species, beyond the emerald ash borer and the Asian longhorned beetle, which are currently the only invasive invertebrate species proposed. The commenter also requested clarity on the entity that can add invasive species that would require the submission of product performance data to the Agency to support efficacy claims—specifically including registrants if third parties are involved. The Agency did not propose to codify a process whereby additional invasive exotic species are added to a defined list of species requiring submission of efficacy data. 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 to support registration of the pesticide product. 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.

A pest's status as an invasive exotic species is just one factor that may warrant submission of product performance data so that EPA can make the requisite statutory findings under FIFRA. EPA does not anticipate requiring data for invasive exotic species solely because they are invasive exotic species. EPA anticipates requiring submission of data for invasive exotic species when they are likely to have significant ecological or economic impacts, or when EPA determines they are pests of significant health importance. As with the emerald ash borer and Asian longhorned beetle, whether the efficacy of the products can be determined at the time of application is one factor EPA takes into consideration when determining if submission of efficacy data is necessary to make the requisite findings under FIFRA.

Commenters asked questions about the flexibilities included in the proposed rule and in part 158 generally. One commenter indicated that 40 CFR 158.1700, which states ''[t]he 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'' gives the reviewer too much discretion to require additional data. First, notwithstanding the provisions that EPA is finalizing in this action, registrants are required to generate, and make available to the Agency on request, data to support all pests for which claims are made on the label. Moreover, the provision cited by the commenter is merely intended to echo currently existing provisions (see, *e.g.,* 40 CFR 158.30, 158.400(d), footnote 1) and allow EPA to maintain the flexibility it needs to make the requisite scientific findings under FIFRA in the face of emerging pests. Conversely, the provisions at 40 CFR 158.1707 and 40 CFR 158.45 allow entities to request a modification of data requirements or a waiver from those requirements that they believe are not appropriate for the unique circumstances of their products. In those cases, EPA has the discretion to grant such a modification request or waiver when the modified or the existing data available would be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment.

One commenter asks that EPA clarify the requirements of the rule as they pertain to existing pesticides. The commenter states that there are many situations in which the historical efficacy data for an existing EPA approved pesticide has been sufficient to reliably substantiate the claims of the pesticide's effectiveness, even when the data do not meet the testing methods and documentation proposed by the rule. Applying the provisions of the proposed rule retroactively to these existing pesticides would be unnecessary, creating a financial burden for the registrant and additional cost to the end-user without added benefit. One commenter disagrees that the proposed regulatory requirements are consistent with EPA's current practices for wood preservatives and pressure-treated wood products.

While EPA has the authority to issue a data call-in (DCI) for a particular product, because the provisions of this rule reflect the longstanding data-needs of the Agency, EPA expects that the Agency already has the necessary data for most of existing pesticide products covered by this rule. EPA notes that as part of the economic analysis conducted in support of this rulemaking, EPA looked at a sampling of more than 30 data package submissions and did not find any that did not meet the requirements as encompassed by the rule, although EPA did find some that had submitted extra data beyond what this rule requires.

C. Comments Outside the Scope of This Rule

EPA received several comments on documents that are outside the scope of the proposed rule, but nonetheless of interest to stakeholders. EPA received comments on Pesticide Registration Notice (PRN) 2002–1: List of Pests of Significant Public Health Importance and on topics covered by the Series 810—Product Performance Test Guidelines. EPA did not propose to modify these guidance documents and is not doing so in this final rule. Likewise, EPA is not establishing or revisiting a process whereby these guidance documents may be modified. Because the topics raised may be of interest to stakeholders, EPA is summarizing these comments and providing clarifying information on the scope of these documents and how they are related to the final regulatory provisions.

One commenter stated that pests of public health significance will evolve over time and requests clarity on how

the list of pests of significant public health importance will be updated to include emerging public health pests. The commenter requests a clear process for reviewing and, if needed, updating the list at least every five years. The commenter states that the addition of pests of public health significance, should be a collaborative process with stakeholder engagement.

PRN 2002–1: List of Pests of Significant Public Health Importance is a guidance document published in accordance with section 28(d) of FIFRA which requires the EPA in coordination with the United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA), to identify pests of significant public health importance and, in coordination with the Public Health Service, to develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to combat and control such pests of public health importance. The contents of the list are both over inclusive and under inclusive of the types of pests covered by this rulemaking. The list covers non-invertebrate pests of significant publish health importance such a fungi, bacteria and mammalian pests; but the list does not cover the wood-destroying insects covered by this action. This list is intended to be a reference document, and inclusion on the list does not affect the regulatory status of any registration or application for registration of any pesticide product.

Because the list itself is outside the scope of this action, EPA is not modifying the list or codifying a new process for modifying the list. EPA acknowledges that changes in pest pressures brought about by climate change or other factors may necessitate seeking product performance data during the registration process to address concerns about efficacy of pesticides for use against a pest not listed in the PRN or in this rule. EPA agrees that it may be appropriate to update the PRN and the rule to include these new pests over time. In fact, in 2020, EPA solicited comment on updating the PRN for the first time in roughly twenty years (see proposed rule at page 70146) and the Agency is currently in the process of developing the final guidance revisions.

Updates of PRNs are done in accordance with PRN 2003–3: Procedural Guidance for EPA's Office of Pesticide Programs Procedures Concerning the Development, Modification, and Implementation of Policy Guidance Documents. EPA's Office of Pesticide Programs (OPP) thinks that public involvement in the development of all types of policy guidance documents is useful. Therefore, OPP's general practice is to provide notice and an opportunity for public comment as early as practicable and appropriate in the development of all significant new pesticide policy guidance documents or significant modifications to such policy guidance documents.

Several commenters raised issues on topics covered by the Series 810—Product Performance Test Guidelines (*e.g.,* time to mortality, use of field versus semi-field tests, which sex to use, adults versus juveniles, etc.) and one commenter requested that EPA adopt separate industry developed testing protocols for wood-destroying insects. EPA did not propose to modify these guidance documents or to adopt new testing protocols and is not doing so in this final rule. While EPA encourages the use of these test guidelines, their use is not mandated by these regulations.

With respect to the comment that EPA should reference Wood Protection Association (AWPA) standards, EPA acknowledges that the National Technology Transfer Advancement Act (NTTAA) directs federal agencies to use technical standards developed or adopted by voluntary consensus standards bodies if compliance would not be inconsistent with applicable law or otherwise impracticable. However, part 158 was never intended to mandate specific testing protocols. The purpose of part 158 is to describe the minimum data and information EPA typically requires. Part 158 ''does not include study protocols, methodology, or standards for conducting or reporting test results'' (40 CFR 158.1(b)(3)). EPA is not deviating for this longstanding structure for part 158 in this action.

The OCSPP test guidelines serve as a compendium of accepted scientific methodologies for research intended to provide data to inform regulatory decisions under TSCA, FIFRA, and/or the FFDCA. These documents provide guidance for conducting appropriate tests, and are also used by EPA, the public, and the companies that are required to submit data under FIFRA. The methods described in these guidelines are strongly recommended for generating the data that are the subject of the guidelines, but EPA recognizes that departures may sometimes be appropriate. Applicants may propose alternatives to the protocols described in the OCSPP test guidelines, with supporting rationale. The Agency assesses such proposals and does, where appropriate, accept data generated from protocols that deviate from OCSPP guidelines. The applicants may submit a protocol of their own devising for Agency review prior to conducting the study, and such submission is subject to a PRIA fee.

V. 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. U.S. EPA. Cost Analysis of the Final Product Performance Rule, prepared by the Biological and Economic Analysis Division, Office of Pesticide Programs, available in docket: EPA–HQ–OPP–2020–0124.
2. U.S. 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. U.S. EPA. PRN 96–7 Termiticide Labeling, available at *https://www.epa.gov/pesticide-registration/prn-96-7-termiticide-labeling* (accessed March 13, 2020).
4. U.S. EPA. Pesticide Product Performance Data Requirements Rule Response to Comments Document, available in docket: EPA–HQ–OPP–2020–0124.
5. U.S. EPA. Mao, Gregg Henderson, Clay W. Scherer. 2011. Toxicity of Seven Termiticides on the Formosan and Eastern Subterranean Termites, Journal of Economic Entomology, Volume 104(3) pp. 1002–1008, *available at https://doi.org/10.1603/EC11005.*
6. Su, N.Y., and R.H. Scheffrahn. 1991. Laboratory Evaluation of Two Slow-acting Toxicants Against Formosan and Eastern Subterranean Termites (isoptera: Thinotermitidae). Journal of Economic Entomology, Volume 84 (1) pp. 170–175. doi: 10.1093/jee/84.1.170.
7. U.S. EPA. OPPTS Guideline 810.3800—Methods for Efficacy Testing of Termite Baits (August 2004).
8. Association of Structural Pest Control Regulatory Officials (ASPCRO) Termiticide Standards Committee, Termiticide Performance Standards, August 5, 2010; *available at https://aspcro.org/wp-content/uploads/2020/12/supdocStatementofPurpose TLRC20100829.pdf.*
9. U.S. EPA. Supporting Statement for an Information Collection Request (ICR) Rule-related ICR Amendment for Pesticide Product Performance Data

Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests (EPA ICR No.: 0277.23; OMB Control No.; 2070–0060).

VI. FIFRA Review Requirements

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

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.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. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted to OMB for approval under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA is assigned EPA ICR No. 0277.23 and OMB Control No.: 2070–0060 (Ref. 9). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information collection activities in this 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. 0277.23). As such, this ICR is intended to amend that existing ICR at the final rule stage, incorporating the information collection activities attributable to this 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 potential respondent groups: 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: Mandatory. 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 of products covered by this rule 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: This 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 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 supporting statement (Ref. 5), 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 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 supporting statement (Ref. 5), $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. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. 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, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden on the small entities subject to the rule. EPA's small entity analysis suggests that the greatest impact, and the most potential cost savings, will 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 will 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 this rule will 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 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, as defined by the RFA will experience cost savings each year as a result of this rule.

While not every element of the rule will result in savings for registrants, EPA conservatively estimates that the rule will 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 this 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.

D. 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. This rule will 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 rule is not subject to the requirements of UMRA sections 202, 203, or 205. The cost analysis for this action is summarized in Unit I.E. and is available in the docket.

E. 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.

F. 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.

G. 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.

H. 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.

I. 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.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14008: Tackling the Climate Crisis at Home and Abroad

In accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14008 (86 FR 7619, January 27, 2021), EPA finds that this action will not result in disproportionately high and adverse human health, environmental, climate-related, or other cumulative impacts on disadvantaged communities because this action does not establish an environmental health or safety standard. Rather, it codifies existing practices in terms of the efficacy data that EPA will typically need to register a product with a claim for one of the covered pests. The Agency notes, that the requirements in this final rule will provide data that will be used to assure that pesticide products perform effectively if claiming effectiveness against an invertebrate pest of significant public health or economic importance, and to address both health concerns and economic consequences stemming from pesticide products that might not perform as claimed on the label, including consequences for sensitive subpopulations and minority or low-income communities.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 158—DATA REQUIREMENTS FOR PESTICIDES

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

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

■ 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 subpart R to read as follows:

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

Sec.

§ 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) *Data requirements.* 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. For pests listed as part of a group or subgroup, pest-specific data would also need to be submitted to support a pest-specific 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.

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 specified 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 a 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 breed 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.

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.

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.

Wood protectants and other non-structural protection means the prevention of termite or other wood-destroying pest activity only to the treated wood (or other treated material), whereas structural protectants, however applied, claim to prevent damage to the structure.

§ 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 158.1786, the performance standards of paragraphs (b) and (c) of this section 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 this part 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 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 §§ 158.1712 through 158.1786, a minimum performance standard of 90 percent is required, except skin-applied insect repellents as specified in paragraph (b) of this section, and non-wearable spatial repellents, where a minimum performance standard of 75 percent is required.

§ 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 modified 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 in the same manner as waiver requests submitted under 40 CFR 158.45. EPA will respond in writing to those requests. The Agency may grant the request if it finds such modifications are appropriate for the pesticide in question, and 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 test data conducted with the species specific to the disease vector claim and meeting the specific performance standard for that species is required even if the disease vector species is not the test species 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 TO PARAGRAPH (b)—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*).

TABLE 1 TO PARAGRAPH (b)—REQUIRED TEST SPECIES FOR PRODUCTS MAKING A CLAIM AGAINST MITES—Continued

[Excluding chiggers]

Labeling claim	Required test species
Dust Mite	Testing on one of the following species is required: American house dust mite (*Dermatophagoides farinae*) OR 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, the performance standard is 100 percent.

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

§ 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 TO PARAGRAPH (b)—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: Blacklegged tick (*Ixodes scapularis*) AND Lone star tick (*Amblyomma americanum*). AND One of the following three species: American dog tick (*Dermacentor variabilis*) OR Brown dog tick (*Rhipicephalus sanguineus*) OR Rocky Mountain wood tick (*Dermacentor andersoni*).
Cattle Ticks	Testing on one of the following species is required: Southern cattle tick (*Rhipicephalus microplus*) OR 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 one of the following test species: Striped bark scorpion (*Centruroides vittatus*) or Arizona bark scorpion (*Centrurioides sculpturatus*).

§ 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 TO PARAGRAPH (b)—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: Brown recluse spider (*Loxosceles reclusa*). AND One of the following species is required: Northern black widow spider (*Latrodectus variolus*) OR Southern black widow spider (*Latrodectus mactans*) OR Western black widow spider (*Latrodectus hesperus*).
Pest Sub-Group Claims	
Black Widow Spiders	Testing on one of the following species is required: Northern black widow spider (*Latrodectus variolus*) OR Southern black widow spider (*Latrodectus mactans*) OR Western black widow spider (*Latrodectus hesperus*).

TABLE 1 TO PARAGRAPH (b)—REQUIRED TEST SPECIES FOR PRODUCTS MAKING A CLAIM AGAINST SPIDERS—Continued

Labeling claim	Required test species
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 TO PARAGRAPH (b)—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: House centipede (*Scutigera coleoptrata*) OR Florida blue centipede (*Hemiscolopendra marginata*) OR *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 TO PARAGRAPH (b)—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: Head louse (*Pediculus humanus capitis*) OR 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 TO PARAGRAPH (b)—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: 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.

(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 TO PARAGRAPH (b)—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: American cockroach (*Periplaneta americana*) AND 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 TO PARAGRAPH (b)—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: Horse bot fly (*Gasterophilus intestinalis*) OR Throat bot fly (*Gasterophilus nasalis*) OR Nose bot fly (*Gasterophilus haemorrhoidalis*).
Human bot fly	Human bot fly (*Dermatobia hominis*).
Keds	Testing is required on the following species: Sheep ked (*Melophagus ovinus*).
Screwworms	Testing is required on one of the following species: Screwworm (*Cochliomyia hominivorax*) OR Secondary screwworm (*Cochliomyia macellaria*).

§ 158.1752 Flies.

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

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

TABLE 1 TO PARAGRAPH (b)—REQUIRED TEST SPECIES FOR PRODUCTS MAKING A CLAIM AGAINST FLIES

Labeling claim	Required test species
Pest Group Claim	
Flies	Testing of five species is required: House fly (*Musca domestica*) AND Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other genera of flesh flies) OR Blow fly (*Phaenicia* sp., *Calliphora* sp., and other genera of blow flies) AND Stable fly (*Stomoxys calcitrans*) AND Biting midge (punkie, granny nipper, no-see-um) (any *Culicoides* sp.) OR Black fly (any *Simulium* sp. or *Prosimulium* sp.) OR Black gnat (any *Leptoconops* sp.) AND Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*).
Pest Sub-Group Claims	
Filth Flies	Testing on two species is required: House fly (*Musca domestica*). AND One of the following species is required: Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies) OR Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies).
Biting flies (excluding Sand flies)	Testing is required on three species: Stable fly (*Stomoxys calcitrans*)

TABLE 1 TO PARAGRAPH (b)—REQUIRED TEST SPECIES FOR PRODUCTS MAKING A CLAIM AGAINST FLIES—Continued

Labeling claim	Required test species
Large Biting Flies	AND one of the large biting fly species: Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*). AND one of the small biting fly species: Biting midge (punkie, granny nipper, no-see-um) (any *Culicoides* sp.) OR Black fly (any *Simulium* sp. or *Prosimulium* sp.) OR Black gnat (any *Leptoconops* sp.). Testing is required on two species: Stable fly (*Stomoxys calcitrans*). AND one of the following species: Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*).
Small Biting Flies (excluding Sand flies).	Testing is required on one of the following species: Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.) OR Black fly (*Simulium* sp. OR *Prosimulium* sp.) OR Black gnat (*Leptoconops* sp.).
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*).
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: *Simulium* sp. OR *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: Black horse fly (*Tabanus atratus*), OR Striped horse fly (*Tabanus lineola*).
Sand flies	Testing on one of the following species is required: *Lutzomyia* sp. OR *Phlebotomus* sp.
Stable fly	Stable fly (*Stomoxys calcitrans*).

§ 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 TO PARAGRAPH (b)—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. One of the following *Culex* species: *Culex pipiens* OR *Culex quinquefasciatus* OR *Culex tarsalis*. AND one of the following *Aedes* species: *Aedes aegypti* OR *Aedes albopictus*. AND one of the following *Anopheles* species: *Anopheles albimanus* OR *Anopheles freeborni* OR *Anopheles gambiae* OR *Anopheles hermsi* OR *Anopheles punctipennis* OR *Anopheles quadrimaculatus* OR *Anopheles stephensi*.

§ 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 TO PARAGRAPH (b)—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 TO PARAGRAPH (b)—REQUIRED TEST SPECIES FOR PRODUCTS MAKING A CLAIM AGAINST 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) of this section. The group and sub-group claims in this paragraph are for direct kill and residual surface application claims against foraging ants only (excluding colony claims).

TABLE 1 TO PARAGRAPH (b)—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: Pharaoh ant (*Monomorium pharaonis*) AND Red imported fire ant (*Solenopsis invicta*).
Pest Sub-Group Claim	
Fire and Harvester	Testing is required on the following species: Red imported fire ant (*Solenopsis invicta*).
Fire ants	Testing is required on the following species: 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 for each species listed or each representative species, in the case of a group. 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) of this section are for direct kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed or each representative species, in the case of a group.

§ 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.

(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) of this section.

TABLE 1 TO PARAGRAPH (b)—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: Two Yellowjacket species (one *Vespula* sp. AND the Bald-faced hornet (*Dolichovespula maculata*)) AND 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 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. The group and sub-group claims in this paragraph are for direct kill and residual surface application claims against foraging ants only (excluding colony claims).

TABLE 1 TO PARAGRAPH (b)—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: Black carpenter ant (*Camponotus pennsylvanicus*) OR Florida carpenter ant (*Camponotus floridanus*) OR 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 and in paragraphs (d) and (e)of this section. The performance standards for labeling claims not covered in this section appear in § 158.1704.

TABLE 2 TO PARAGRAPH (c)—PERFORMANCE STANDARDS FOR CERTAIN CLAIMS AGAINST CARPENTER ANTS

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

(d) *Colony Claims.* For colony claims, testing must be done for each species listed or each representative species, in the case of a group.

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

§ 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 TO PARAGRAPH (b)—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: Anobiid beetle (*Anobiidae* sp.) AND Bostrichid beetle (*Bostrichidae* sp.) AND 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 TO PARAGRAPH (c)—PERFORMANCE STANDARDS FOR CERTAIN CLAIMS AGAINST WOOD-DESTROYING BEETLES

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

§ 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. For the structural protection and wood preservative claim categories, a claim against any specific genus of subterranean termite must be supported by data on that individual genus and all the required test genera for a subterranean termite claim must be tested and submitted.

TABLE 1 TO PARAGRAPH (b)—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: Testing is required on the following *Coptotermes* termite: *Coptotermes formosanus* AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus* AND one of the following arboreal termite species: *Nasutitermes corniger* AND one of the following drywood termite species: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi*.
Pest Sub-Group Claim	
Arboreal Termites	Testing of one arboreal termite species is required: *Nasutitermes corniger.*
Dampwood Termites	Testing of the following dampwood termite is required: *Zootermopsis* sp.
Drywood Termites	Testing of one of the following drywood termites is required: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi.*
Subterranean Termites, including Formosan Subterranean Termites.	Testing in two genera of termites is required: Testing on the following *Coptotermes* species is required: *Coptotermes formosanus*AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus.*

(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 TO PARAGRAPH (c)—PERFORMANCE STANDARDS FOR CERTAIN CLAIMS AGAINST TERMITES

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

■ 5. Revise § 158.2070 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 and performance standards 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. However, data requirements and the performance standards that determine the acceptability of data may be waived or modified on a case-by-case basis pursuant to the waiver provisions in § 158.45 and modification provisions in § 158.1707.

(c) *Product performance data for each product that bears a public health pest 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 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 and the performance standards 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 § 158.45 and the provisions in § 158.1707.

(c) *Product performance data for each product that bears a public health pest 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) to read as follows:

§ 158.2200 Applicability.

* * * * *

(b) A product that bears both antimicrobial and non-antimicrobial uses or claims 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.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 220407–0086]

RIN 0648–BJ87

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Lighthouse Repair and Tour Operations at Northwest Seal Rock, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule; notification of issuance.

SUMMARY: NMFS Office of Protected Resources, upon request from the St. George Reef Lighthouse Preservation Society (Society), hereby issues regulations to govern the unintentional taking of marine mammals incidental to conducting aircraft operations, lighthouse renovation, light maintenance activities, and tour operations on the St. George Reef Lighthouse Station (Station) on Northwest Seal Rock (NWSR) over the course of five years (2022–2027). These regulations, which allow for the issuance of Letters of Authorization (LOA) for the incidental take of marine mammals during the described activities and specified timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as requirements pertaining to the monitoring and reporting of such taking. We are also issuing a Letter of Authorization to cover the first year of these activities.

DATES: Effective from May 15, 2022 through May 14, 2027.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Regulatory Action

This final rule establishes a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to the Society conducting aircraft operations, lighthouse renovation, light maintenance activities, and tour operations on the Station on NWSR approximately 8 miles (12.9 km) northwest of Crescent City, CA.

We received an application from the Society requesting 5-year regulations and authorization to take multiple species of marine mammals. Take would occur by Level B harassment incidental to acoustic and visual disturbance of pinnipeds during helicopter operations, lighthouse repair, and tour operations. Please see Background section below for definitions of harassment.