• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 29, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file any comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 12, 2013.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart RR—Tennessee

■ 2. Section 52.2220(c) is amended by revising entries in Table 3 for ''Sections 25.0 and 46.0'' to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

TABLE 3—EPA APPROVED KNOX COUNTY, REGULATIONS

State section	Title/Subject	State effective date	EPA Approval date	Explanation
* *	*	*	* *	*
Section 25.0	Permits	10/10/2012	2/28/13 [Insert first page of publication].	
* *	*	*	* *	*
Section 46.0	Regulation of Volatile Organic Compounds.	8/12/2009	2/28/13 [Insert first page of publication].	
* *	*	*	* *	*

* * * * *

[FR Doc. 2013–04412 Filed 2–27–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 158 and 161

[EPA–HQ–OPP–2010–0427; FRL–9372–7]

RIN 2070–AJ26

Declaration of Prion as a Pest Under FIFRA; Related Amendments; and Availability of Final Test Guidelines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this final rule EPA declares a prion (*i.e.,* proteinaceous infectious particle) to be a ''pest'' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and amends the regulations to expressly include prion within the regulatory definition of pest. This final rule also amends existing pesticide product performance data requirements to clarify that efficacy data are required for pesticide products with prion-related claims. In addition, EPA is announcing the availability of final test guidelines on generating the product performance data for prion-related pesticide products.

DATES: This final rule is effective April 29, 2013.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2010–0427, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in the EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.* In addition to being available in the docket, a copy of the final test guidelines titled ''Product Performance Test Guidelines, OCSPP 810.2700: Products with Prion-Related Claims'' is available online at *http://epa.gov/ocspp/pubs/frs/home/testmeth.htm.*

FOR FURTHER INFORMATION CONTACT: Melba Morrow, Antimicrobials Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–2716; fax number: (703) 308–6467; email address: *morrow.melba@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you apply for or own pesticide registrations. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document might apply to them. Potentially affected entities may include, but are not limited to:

- Producers of pesticide products (NAICS code 32532).
- Producers of antimicrobial pesticides (NAICS code 32561).
- Veterinary testing laboratories (NAICS code 541940).
- Medical pathology laboratories (NAICS code 621511).
- Taxidermists, independent (NAICS code 711510).
- Surgeons (NAICS code 621111).
- Dental surgeons (NAICS code 621210).

B. What is the agency's authority for taking this action?

This action is issued under the authority of sections 2 through 34 of FIFRA (7 U.S.C. 136–136y). In particular, the final rule is issued pursuant to FIFRA section 25(a) (7 U.S.C. 136w(a)).

C. What action is the agency taking?

EPA declares a prion (*i.e.,* proteinaceous infectious particle) to be a ''pest'' under FIFRA, and amends its regulations to expressly include prion within the regulatory definition of pest. Since 2003, EPA has considered a prion to be a pest under FIFRA, so a product intended to reduce the infectivity of any prion on inanimate surfaces (*i.e.,* a ''prion-related product'') is considered to be a pesticide and regulated as such. Any company seeking to distribute or sell a pesticide product regulated under FIFRA must, subject to some possible exceptions, obtain a section 3 registration, section 24(c) registration, or a section 18 emergency exemption before it can be distributed or sold in the United States. This rule codifies the Agency's current interpretation of FIFRA with respect to prions. The amendment of the definition of ''pest'' in EPA's regulations, together with the formal declaration under FIFRA section 25(c)(1) that a prion is a pest, eliminates any confusion about the status of prion-related products under FIFRA. Regulating prion-related products under FIFRA is appropriate for protecting human health and the environment against unreasonable adverse effects and ensuring that such products are effective.

EPA is also amending its product performance data requirements to clarify that efficacy data are required for all products with prion-related claims. The existing product performance data requirements already require efficacy data to be submitted when the ''pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment * * * .'' Since this general product performance data requirement applies to products with prion-related claims, EPA is amending the regulation to specifically identify the efficacy data that are required for products with prion-related claims. In addition, EPA is announcing the availability of final test guidelines concerning the generation of product performance data for prion-related products.

D. What are the incremental costs and benefits of this action?

This final rule will: (a) Codify the Agency's current interpretation of FIFRA by adding ''prion'' to the list of pests in 40 CFR 152.5, and (b) amend the pesticide data requirement regulations to clarify that efficacy data are required to support the registration of all end-use products which bear label claims to reduce the infectivity of prions. The qualitative benefits of this final rule relate to the protection of human health and the environment by subjecting prion-related products to regulation under FIFRA, including all data and labeling requirements. The incremental costs of this rule are estimated to range from $424,000 to $4.72 million per pesticide registration action. See also Unit VI.A.

II. Background

A. What is a prion?

Prions (proteinaceous infectious particles) may occur in the central nervous system tissues of animals as an abnormal (misfolded), infectious form of prion protein.

Prion protein in its normal form, or conformation, can be designated PrP^{c} (cellular isoform) while abnormal conformations of prion proteins are generally called prions. Different types of prions are commonly designated by the type of diseases they produce, such as PrP^{Sc} (prions associated with scrapie) and PrP^{BSE} (prions associated with bovine spongiform encephalopathy—mad cow disease).

In the disease process, prions (such as PrP^{sc}) recruit normal prion proteins (PrP^{c}) and convert them into prions (*e.g.,* another copy of PrP^{Sc}). This recruitment and conversion process results in the progressive accumulation of disease-producing prions. When this process takes place in the brain, it causes disease that slowly progresses from neuronal dysfunction and degeneration to death. These neurodegenerative prion diseases are known collectively as transmissible spongiform encephalopathies (TSE). TSEs include scrapie disease in sheep, bovine spongiform encephalopathy (BSE) in cattle, chronic wasting disease (CWD) in deer and elk, kuru and variant Creutzfeld-Jakob Disease (vCJD) in humans, and similar diseases in other animals. EPA and other agencies are concerned that animal-related prions may spread to other animals (*e.g.,* scrapie among sheep, CWD among cervids) or to humans (*e.g.,* BSE), and that human-related prions may be passed to other humans (*e.g.,* kuru or vCJD). These diseases are always fatal in humans and animals alike, and there are no known treatments or cures.

B. Regulatory History of Products With Prion-Related Claims

On September 10, 2003, EPA determined that a prion should be considered to be a ''pest'' under the FIFRA (7 U.S.C. 136 *et seq.*) and that products intended to inactivate prions (*i.e.,* ''prion-related products'') should be regulated under FIFRA (Ref. 1).

In the **Federal Register** issue of January 26, 2011 (76 FR 4602) (FRL–8850–4), to eliminate any confusion about the status of prion-related products under FIFRA, EPA issued a proposed rule that, when finalized, would declare a prion a ''pest'' under FIFRA pursuant to the authority of FIFRA section 25(c)(1), and amend EPA's regulations to expressly include prion within the regulatory definition of pest. EPA currently considers a prion to be a pest under FIFRA; in addition, a product intended to reduce the infectivity of any prion on inanimate surfaces (*i.e.,* a ''prion-related product'') is considered to be a pesticide and regulated as such. Subject to some exceptions, any pesticide product must be registered or exempted under FIFRA sections 3, 24(c), or 18 before the product may be distributed or sold in the United States.

In the **Federal Register** issue of November 17, 2011 (76 FR 71294) (FRL–8886–1), as a supplement to the proposed rule to declare a prion (*i.e.,* proteinaceous infectious particle) a ''pest'' under FIFRA, and to amend its regulations to expressly include prion with the regulatory definition of pest (January 26, 2011; 76 FR 4602), EPA proposed to amend its product performance data requirements in 40 CFR parts 158 and 161 to clarify that efficacy data are required for all products with prion-related claims. The existing product performance data requirements already require efficacy data to be submitted when the ''pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment * * * .'' Since this general product performance data requirement applies to products with prion-related claims, EPA proposed to amend the regulation to specifically identify the efficacy data required for products with prion-related claims. In addition, EPA announced the availability for public review and comment of draft test guidelines concerning the generation of product performance data for prion-related products.

C. Data Requirements for Pesticides

First promulgated in 1984, EPA's pesticide data requirements outline the kinds of data and related information typically needed to register a pesticide. Since there is much variety in pesticide chemistry, exposure and hazard, the requirements are designed to be flexible. Test notes to the data requirements tables and other information in the regulation explain the conditions under which data are typically needed. Essentially, the data requirements identify the questions that the applicant will need to answer regarding a pesticide product before the Agency can consider it for registration.

At this time, the data requirements for conventional, biochemical, and microbial pesticides are codified in 40 CFR part 158, and data requirements for antimicrobial pesticides are codified in 40 CFR part 161. In addition, part 158 contains general provisions concerning data for the pesticides covered by the regulation (subpart A), instructions on how to use the data tables in the regulation (subpart B), and a series of data tables that identify data requirements tailored to specific kinds of pesticides, *i.e.,* conventional pesticides (subparts D–O), biochemical pesticides (subpart U), microbial pesticides (subpart V), and several reserved subparts as placeholders for future tailoring of the data requirements that is underway to facilitate the utility of the data tables for pesticide registrants, such as reserved subpart W for antimicrobials.

On October 26, 2007, EPA revised the structure of part 158 and the data requirements for conventional pesticides (72 FR 60934), and biochemical pesticides and microbial pesticides (72 FR 60988). In conjunction with those revisions, EPA also transferred intact the original 1984 pesticide data requirements that had been in part 158 into a new part 161, titled ''Data Requirements for Antimicrobial Pesticides'' (72 FR 60251, October 24, 2007). In essence, part 161 is intended to be transitional by preserving the existing data requirements applicable to antimicrobial pesticides until a new final regulation that tailors the data requirements for antimicrobial pesticides is promulgated. On October 8, 2008 (73 FR 59382), EPA proposed to establish data requirements specific to antimicrobial pesticide chemicals in 40 CFR part 158, subpart W and to remove 40 CFR part 161. To date, these proposed changes have not been promulgated.

D. Test Guidelines Used To Develop Data for Submission to EPA

EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) has issued a series of harmonized test guidelines for use in the testing of pesticides and toxic substances, and the development of test data for submission to the Agency. The OCSPP test guidelines are documents that specify methods that EPA recommends be used to generate data that are submitted to EPA to support the registration of a pesticide under FIFRA (7 U.S.C. 136 *et seq.*), setting of a tolerance or tolerance exemption for pesticide residues under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a), or regulatory activities for other chemical substances under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*). The OCSPP harmonized test guidelines serve as a compendium of EPA-accepted scientific methodologies and protocols for conducting the studies routinely used for generating data on pesticides and industrial chemicals regulated under FIFRA, FFDCA, and TSCA, and may also be useful for voluntary testing purposes. The OCSPP harmonized test guidelines can be accessed online at *http://epa.gov/ocspp/pubs/frs/home/testmeth.htm.*

III. Public Comments on the Proposed Rules

All of the comments submitted to EPA on both of the proposed rules are included in the docket for this rulemaking under docket ID number EPA–HQ–OPP–2010–0427. EPA prepared two Response to Comment documents that summarize the comments received and provide EPA's detailed responses to all comments received. This unit discusses, in general terms, the public comments and EPA's responses to those comments.

A. Public Comments on the January 2011 Proposal

In response to the January 2011 proposed rule, six parties submitted comments—one in favor, four against, and one neutral. The commenter in favor of the proposed rule expressed concern about the threat posed to human health from prions and the need to use an existing regulatory scheme to assure protection of public health. The commenters disagreed with the proposed rule and cited a range of reasons: Poor statutory analysis, use of regulatory authority to modify the intent of Congress and to bypass the lawmaking processes, declaring prions to be pests even though they are not

alive, and declaring a prion to be a pest could lead to further declarations that other non-living materials are pests. EPA's responses to these comments may be found in the document titled ''EPA, Office of Pesticide Programs (OPP), Responses to Comments Received Concerning 'Declaration of Prion as a Pest Under FIFRA and Amendment of EPA's Regulatory Definition of Pests to Include Prion.' '' (Ref. 2). Overall, EPA was not persuaded by the negative comments to not issue the final rule as proposed.

B. Public Comments on the November 2011 Supplemental Proposed Rule

In response to the November 2011 supplemental proposed rule (76 FR 71294), two parties submitted comments—one in favor and one against the proposed supplemental rule. The first commenter advocated that EPA regulate all possible prion carriers that have any likelihood of being transmitted to human beings, since the commenter stated that she lost her mother to sporadic Creutzfeldt Jakob Disease. The second commenter expressed opposition to the proposed supplemental rule, submitting the exact same comments that he had submitted previously for the proposed rule. EPA's responses to these comments may be found in the document titled ''EPA, Office of Pesticide Programs (OPP), Responses to Comments Received Concerning 'Prions: Proposed Amendment to Clarify Product Performance Data for Products With Prion-Related Claims and Availability of Draft Test Guidelines' '' (Ref. 3). Overall, EPA was not persuaded by the negative comment to not issue the changes to EPA's existing regulations as proposed.

IV. The Final Rule

EPA is finalizing the proposed changes as proposed. Specifically, EPA has determined that under FIFRA a prion is considered to be a pest; thus, pursuant to the authority of FIFRA section 25(c)(1), EPA is declaring a prion to be a pest. For the same reasons, EPA is amending the regulatory definition of ''pests'' in 40 CFR 152.5 to expressly include ''prion.'' These actions make explicit the Agency's authority to regulate products distributed or sold for the purpose of reducing the infectivity of prions (*i.e.,* prion-related products), other than prions on or in living humans or other living animals and those on or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA section 201(g)(1)) and cosmetics (as defined in FFDCA section 201(i)). Prion-related products are already regulated under FIFRA and subject to all requirements and provisions of the Act based on EPA's September 10, 2003 decision (Ref. 1) that prions share enough characteristics of an ''other micro-organism'' or ''form of life'' (as those terms are used in FIFRA) to fall within the scope of FIFRA section 2(t) and 40 CFR 152.5(d). This rule ensures that the regulatory definition reflects the Agency's authority to regulate prion-related products. The primary impact of declaring that a prion is a pest and including ''prion'' in the regulatory definition of ''pest'' is to provide regulatory clarity that prion-related products must be registered under FIFRA sections 3 or 24(c), or otherwise exempted before such products may be distributed or sold in the United States.

EPA is also amending its pesticide data requirement regulations to clarify that efficacy data are required to support the registration of all end-use products that are intended to be used on inanimate items and/or environmental surfaces, and which bear label claims to reduce the infectivity of prions. Specifically, EPA is amending the data requirements for product performance testing that are currently found in 40 CFR 158.400 and 40 CFR 161.640 by inserting an entry in the data tables to more clearly specify that efficacy data are required for prion-related products.

Currently, EPA's regulations at 40 CFR 158.400(e)(1) and 40 CFR 161.640(b)(1) require efficacy data to be submitted when the ''pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment * * * .'' Because a prion-related product bears a claim to reduce the infectivity of prions (that poses a threat to human health), an applicant or registrant is required by existing regulations to submit valid data that demonstrate that its prion-related product is effective. As such, today's amendment to the data requirements simply provides more specificity for those who are considering whether to register a product for use on inanimate items and/or environmental surfaces and make claims that the product will reduce the infectivity of prions. In summary, EPA is clearly specifying that efficacy data are required for prion-related products by inserting a new entry in the data tables that are currently found in 40 CFR 158.400 and 40 CFR 161.640.

EPA is also announcing the availability of final test guidelines that the Agency now includes in the OCSPP harmonized test guidelines described in this Unit II.D., as part of the 810 Series of Product Performance Test Guidelines. Specifically, the final guidelines address product performance tests for products with prion-related claims and are identified as ''Product Performance Test Guidelines; OCSPP 810.2700: Products with Prion-Related Claims'' (Ref. 4). The guidelines for products with prion-related claims provide guidance concerning the data and information needed to assess the efficacy of antimicrobial pesticides intended to be used on inanimate items and/or environmental surfaces, and which bear label claims to reduce the infectivity of prions.

On March 31 and April 1, 2009, EPA presented its draft test guidelines to the FIFRA SAP for peer review (Ref. 5), along with a ''white paper'' summarizing the most relevant scientific studies and publications related to the issue of whether a prion is a pest in support of the separate proposed rule on that issue (Ref. 6). The SAP provided comments on the draft guidance document on June 29, 2009 (Ref. 7). EPA has considered the SAP's recommendations and incorporated changes, as appropriate (Ref. 8). In addition, the draft test guidelines underwent interagency review in 2010.

V. FIFRA Mandated Reviews

In accordance with FIFRA section 25(a) and (d), on August 2, 2012, EPA submitted a draft of this final rule to the Secretary of the Senate, the Clerk of the House of Representatives, the Committee on Agriculture in the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry in the United States Senate, the United States Department of Agriculture (USDA), and the FIFRA Scientific Advisory Panel (SAP). In accordance with FIFRA section 21(b), EPA also submitted a draft of this final rule to the Secretary of Health and Human Services (HHS). The HHS and SAP waived review of this final rule. USDA submitted comments on September 5, 2012, to which EPA responded on December 3, 2012 (see docket noted in **ADDRESSES** above).

VI. Statutory and Executive Order Reviews

This action amends existing regulations to include prion as a pest and to add more specificity regarding an existing efficacy data requirement for products intending to make prion-related claims. It does not otherwise amend or impose any other requirements. This rule does not

otherwise involve any significant policy or legal issues, but does impact existing costs.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and was not therefore submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

EPA prepared an economic analysis of the potential costs associated with this action, titled ''Economic Analysis of the Notice of Proposed Rulemaking Concerning the Status of Prion as a Pest under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).'' The Economic Analysis (EA) presents the Agency's assessment of the potential costs and benefits expected to result from this rule. In terms of benefits, the rule will ensure that EPA can protect human health and the environment by subjecting prion-related products to regulation under FIFRA, including all data and labeling requirements. In terms of costs, using pre-2003 costs as the baseline, the incremental costs of this rule per registration action range from $424,000 to $4.72 million (Ref. 9).

The EA presents the costs of various types of registrations under this rule and presents expected incremental costs for three product registration types. The three types of registration actions which are possible under this rule are the registration of: (1) A new active ingredient, (2) a new use product, or (3) amendment of an existing registration to add a new use.

The EA estimates that three firms might seek registrations for major new use products in the first year. If all uses are high exposure (*e.g.,* indirect food uses) for a new active ingredient, the maximum potential total cost to industry in the first year would be approximately $7.05 million, and costs per firm would be approximately $2.35 million. Given the uncertainty that characterizes the market for prion-related products at this time, the Agency did not speculate further on the expected number of registrations in subsequent years. However, registrations that occur after the initial major new use product registrations would probably be major new use amendments. Data requirements would entail only product-specific efficacy data for major new use amendments at a cost of approximately $431,000 per registration action. Approximately 80% of the firms in the pesticide manufacturing industry are small firms with revenues of $22 million, on average. A cost of $7.05 million suggests that the incremental cost per firm of $2.35 million would equal nearly 11% of annual revenues. However, after the initial three registrations, a major new use amendment at a cost of $431,000 would represent fewer than 2% of average annual revenues.

The EA identifies three categories of persons who could be affected by the rule—pesticide registrants, users of prion-related products, and researchers. The registration-related requirements under FIFRA, however, are imposed on the entity that registers the prion-related product. Users of prion-related products and researchers are affected indirectly. The EA summarizes potential qualitative impacts of regulating prion-related products that were expressed by product users to EPA during its outreach efforts to these users.

B. Paperwork Reduction Act (PRA)

This action does not impose any new significant information collection burden that would require additional review or approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities contained in the regulation are already approved under information collection instruments related to:

1. The submission of data to EPA to establish a tolerance or an exemption from the requirement to have a tolerance currently approved under OMB Control No. 2070–0024 (EPA ICR No. 0597).

2. The activities associated with the application for a new or amended registration of a pesticide currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277).

3. The activities associated with the application for an experimental use permit currently approved under OMB Control No. 2070–0040 (EPA ICR No. 0276).

4. Activities associated with the generation of data in response to a Data-Call-In currently approved under OMB Control No. 2070–0174 (EPA ICR No. 2288).

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 certain EPA regulations in 40 CFR are listed in 40 CFR part 9 and in the **Federal Register**, as appropriate.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act, 5 U.S.C. 551–553, or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201. A small business that manufactures pesticides and other agricultural chemicals as defined by NAICS code 325320 has 500 or fewer employees based on the SBA standards.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The amendments do not change existing impacts. Although no small entities have been identified that are directly affected by these amendments, any such impacts are likely to be minimal. In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and the Agency.

D. Unfunded Mandates Reform Act (UMRA)

Title II of UMRA, 2 U.S.C. 1531–1538, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. Thus, this rule is not subject to the requirements of UMRA sections 202 or 205. This rule is also not subject to the requirements of UMRA section 203, because it contains no regulatory requirements that might significantly or uniquely affect small governments. These amendments are unlikely to affect State, local, and tribal governments at

all, and are likely to affect the private sector only trivially.

E. Executive Order 13132: Federalism

This rule does not have federalism implications 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). State and local governments are rarely pesticide applicants or registrants, so these amendments are not expected to affect these governments. Thus, Executive Order 13132 does not apply to this action.

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). This action will not have substantial direct effects on Indian Tribes, will not significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Tribal governments are rarely pesticide applicants or registrants, so these amendments are not expected to affect these governments. 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 health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045, because it does not establish an environmental standard intended to mitigate health or safety risks, nor is it an ''economically significant regulatory action'' as defined in Executive Order 12866.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of NTTAA, 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve any technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it generally increases the level of protection provided to human health or the environment and thereby not adversely affect any population. This rule does not entail special considerations of environmental justice related issues.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket (under docket ID number EPA–HQ–OPP–2010–0427) 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 contact person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. Environmental Protection Agency. 2004. Considerations of Prions as a Pest under FIFRA. Memorandum to the Record from Susan B. Hazen, Principal Deputy Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances. April 29, 2004.

2. U.S. Environmental Protection Agency. 2012. EPA, Office of Pesticide Programs (OPP), Responses to Comments Received Concerning ''Declaration of Prion as a Pest Under FIFRA and Amendment of EPA's Regulatory Definition of Pests to Include Prion.''

3. U.S. Environmental Protection Agency. 2012. EPA, Office of Pesticide Programs (OPP), Responses to Comments Received Concerning ''Prions: Proposed Amendment to Clarify Product Performance Data for Products With Prion-Related Claims and Availability of Draft Test Guidelines.''

4. U.S. Environmental Protection Agency. 2012. Product Performance Test Guidelines, OCSPP 810.2700: ''Products with Prion-Related Claims.'' Final December 2012.

5. U.S. Environmental Protection Agency. 2009. Product Performance Test Guidelines, Series 810, Draft OCSPP No. 810.XXXX, titled ''Products with Prion-Related Claims.'' Draft dated February 23, 2009.

6. U.S. Environmental Protection Agency. 2009. Scientific Information Concerning the Issue of Whether Prions Are a ''Pest'' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Draft dated December 17, 2008.

7. U.S. Environmental Protection Agency. 2009. Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held March 31–April 1, 2009, on ''Scientific Issues Associated with Designating a Prion as a 'Pest' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and Related Efficacy Test Methods.'' Memorandum from Myrta R. Christian, Designated Federal Official, FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, to Debbie Edwards, Ph.D., Director, Office of Pesticide Programs.

June 29, 2009. See *http://www.epa.gov/scipoly/sap/meetings/2009/march/033109panelmembers.html*.

8. U.S. Environmental Protection Agency. 2010. EPA Responses to Comments by the FIFRA Scientific Advisory Panel Concerning ''Scientific Information Concerning the Issue of Whether Prions Are a 'Pest' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).'' February 17, 2010.

9. U.S. Environmental Protection Agency. 2010. Economic Analysis of the Notice of Proposed Rulemaking Concerning the Status of Prion as a Pest under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

List of Subjects in 40 CFR Parts 152, 158 and 161

Environmental protection, Administrative practice and procedures, Agricultural commodities, Chemical testing, Pesticides and pests, Reporting and recordkeeping requirements, Test guidelines.

Dated: February 21, 2013.

Bob Perciasepe,

Acting Administrator.

Therefore, 40 CFR chapter I is amended as follows:

PART 152—[AMENDED]

■ 1. The authority citation for part 152 continues to read as follows:

Authority: 7 U.S.C. 136–136y; subpart U is also issued under 31 U.S.C. 9701.

■ 2. In § 152.5, revise paragraph (d) to read as follows:

§ 152.5 Pests.

* * * * *

(d) Any fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA section 201(g)(1)) and cosmetics (as defined in FFDCA section 201(i)).

PART 158—[AMENDED]

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

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

■ 4. In § 158.400(d), amend the table under the category ''Efficacy of antimicrobial agents'' by adding a new entry at the end of the category to read as follows:

§ 158.400 Product performance data requirements table.

* * * * *

TABLE—PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline number	Data requirement	Use pattern									Test substance to support		Test note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential outdoor	Indoor	MP	EP	
		Food crop	Non-food crop	Food	Non-food	Food crop	Non-food crop						
Efficacy of antimicrobial agents													
	*	*		*		*		*		*		*	
810.2700	Products with prion-related claims.	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
	*	*		*		*		*		*		*	

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PART 161—[AMENDED]

■ 5. The authority citation for part 161 continues to read as follows:

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

■ 6. In § 161.640, revise the section heading and in paragraph (a) amend the table by adding under the category ''Efficacy of antimicrobial agents'' a new entry at the end of the category to read as follows:

§ 161.640 Product performance data requirements table.

(a) * * *

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Non-food crop	Food	Non-food	Food crop	Non-food crop						
Efficacy of antimicrobial agents													
	*	*		*		*		*		*		*	
Products with prion-related claims.	*	.....	.....	.....	.....	.....	.....	.....	R	.....	EP *	810.2700.	
	*	*		*		*		*		*		*	

* * * * *

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