individual or to granting access to an investigative file pertaining to such individual could:

(i) Interfere with investigative and enforcement proceedings,

(ii) Deprive codefendants of a right to a fair trial or an impartial adjudication,

(iii) Constitute an unwarranted invasion of the personal privacy of others,

(iv) Disclose the identity of confidential sources and reveal confidential information supplied by such sources,

(v) Disclose investigative techniques and procedures.

(3) 5 U.S.C. 552a(e)(1). This provision of the Privacy Act requires each agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or executive order. The reasons for exempting this system of records from the foregoing are as follows:

(i) The IRS will limit the system to those records that are needed for compliance with the provisions of Title 26, 31 U.S.C. 330, and regulations applicable to paid tax return preparers. However, an exemption from the foregoing is needed because, particularly in the early stages of an investigation, it is not possible to determine the relevance or necessity of specific information.

(ii) Relevance and necessity are questions of judgment and timing. What appears relevant and necessary when first received may subsequently be determined to be irrelevant or unnecessary. It is only after the information is evaluated that the relevance and necessity of such information can be established with certainty.

(5) 5 U.S.C. 552a(e)(4)(I). This provision of the Privacy Act requires the publication of the categories of sources of records in each system of records. The reasons an exemption from this provision has been claimed, are as follows:

(i) Revealing categories of sources of information could disclose investigative techniques and procedures.

(ii) Revealing categories of sources of information could cause sources who supply information to investigators to refrain from giving such information because of fear of reprisal, or fear of breach of promises of anonymity and confidentiality.

Treasury will publish the notice of the proposed new system of records separately in the **Federal Register**.

Pursuant to Executive Order 12866, it has been determined that this proposed rule is not a significant regulatory action, and therefore, does not require a regulatory impact analysis. Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601–612, do not apply.

The regulation will not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposed rule does not have federalism implications under Executive Order 13132.

Pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby certified that these regulations will not significantly affect a substantial number of small entities. The proposed rule imposes no duties or obligations on small entities.

List of Subjects in 31 CFR Part 1

Privacy.

Part 1, subpart C of title 31 of the Code of Federal Regulations is amended as follows:

PART 1—[AMENDED]

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

Authority: 5 U.S.C. 301 and 31 U.S.C. 321. Subpart A also issued under 5 U.S.C. 552 as amended. Subpart C also issued under 5 U.S.C. 552a.

2. Section 1.36 paragraph (g)(1)(viii) is amended by adding the following text to the table in numerical order.

§ 1.36 Systems exempt in whole or in part from provisions of 5 U.S.C. 552a and this part.

(g) * * *

(1) * * *

(viii) * * *

Number	Name of system
* * * * *	
IRS 37.111	Preparer Tax Identification Number Records.
* * * * *	

Dated: October 24, 2011.

Melissa Hartman,

Deputy Assistant Secretary for Privacy, Transparency, and Records.

[FR Doc. 2011–29384 Filed 11–16–11; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 158 and 161

[EPA–HQ–OPP–2010–0427; FRL–8886–1]

RIN 2070–AJ26

Prions; Proposed Amendment To Clarify Product Performance Data for Products With Prion-Related Claims and Availability of Draft Test Guidelines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental proposed rule.

SUMMARY: As a supplement to the proposed rule to declare a prion (*i.e.,* proteinaceous infectious particle) a ''pest'' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and to amend its regulations to expressly include prion within the regulatory definition of pest, EPA is now proposing to amend 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 requirement applies to products with prion-related claims, EPA is proposing to amend the regulation to specifically identify that efficacy data are required for products with prion-related claims. In addition, EPA is announcing the availability for public review and comment of draft test guidelines concerning the generation of product performance data for prion-related products.

DATES: Comments must be received on or before January 17, 2012.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0427, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S.

Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0427. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* 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 either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jeff Kempter, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; *telephone number:* (703) 305–5448; *fax number:* (703) 308–6467; *email address: kempter.carlton@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you apply for or own pesticide registrations. 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).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

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). TSE's 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 to sheep, CWD to cervids) or to humans (*e.g.,* BSE), and that human-related prions may be passed to other humans (*e.g.,* kuru or CJD). 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 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and that products intended to inactivate prions (*i.e.,* ''prion products'') should be regulated under FIFRA (Ref. 1).

On 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, 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.

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 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 register it.

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.

On October 26, 2007, EPA revised the structure of part 158 and the data requirements for conventional pesticides (72 FR 60934) (FRL–8106–5), and biochemical pesticides and microbial pesticides (72 FR 60988) (FRL–8109–8). 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, entitled ''Data Requirements for Antimicrobial Pesticides'' (72 FR 60251, October 24, 2007) (FRL–8116–2). 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 part 161.

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 harmonized 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 the decision making process for an industrial chemical under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*).

The OCSPP harmonized test guidelines are developed by EPA scientists and non-EPA individuals with a particular interest or expertise in the subject matter covered, including representatives from the scientific community, industry, non-profit organizations, and other governments. Some of these guidelines harmonize EPA's test methods with guidelines established by the Organization for Economic Cooperation and Development (OECD), an international organization whose membership includes most industrialized nations which maintain comprehensive testing methods for pesticides and industrial chemicals. When necessary, significant scientific issues are presented for external peer review to the FIFRA Scientific Advisory Panel (SAP) or to another group of scientific experts for that particular topic.

The OCSPP harmonized test guidelines serve as a compendium of 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.

Under FIFRA and FFDCA, studies conducted according to the OCSPP test guidelines or another approved protocol may be used in satisfying FIFRA data requirements in 40 CFR part 158 and 40 CFR part 161, Data-Call-In's issued pursuant to FIFRA section 3(c)(2)(B), as needed to satisfy data requirements appropriate for specific pesticide registration applications, or for satisfying data requirements to demonstrate the safety of a tolerance or tolerance exemption under FFDCA section 408.

As a guidance document, the test guidelines are not binding on either EPA or any outside parties. At places in the guidance, the Agency uses the word ''should.'' In the guidance, use of ''should'' with regard to an action means that the action is recommended rather than mandatory. The procedures contained in the test guidelines are recommended for generating the data that are the subject of the test guideline, but EPA recognizes that departures may be appropriate in specific situations. EPA will consider alternatives to the recommendations described in the test guidelines on a case-by-case basis, after assessing whether the alternative will provide the data necessary to inform the regulatory decision that must be made.

The OCSPP harmonized test guidelines can be accessed online at *http://epa.gov/ocspp/pubs/frs/home/testmeth.htm.* Please note that although

collectively referred to as the ''OCSPP Test Guidelines,'' the individual guidelines issued before April 22, 2010, use ''OPPTS'' in the titles. On April 22, 2010, the office name changed from ''Office of Prevention, Pesticides, and Toxic Substances'' or ''OPPTS'' to ''Office of Chemical Safety and Pollution Prevention'' and ''OCSPP.''

III. Proposed Data Requirement

A. 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 proposed rule is issued pursuant to FIFRA section 25(a) (7 U.S.C. 136w(a)).

B. What action is the agency taking?

EPA is proposing to amend 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 proposes to amend 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 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 would bear a claim to reduce the infectivity of prions (that poses a threat to human health), an applicant or registrant would be required by existing regulations to submit valid data that demonstrate that its prion-related product is effective. As such, this amendment 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.

As indicated in Unit II.C., EPA issued a proposed rule in 2008 (73 FR 59382, October 8, 2008) that proposed to codify the data requirements for antimicrobial pesticide chemicals in 40 CFR part 158, subpart W. That 2008 proposed rule also proposed the following:

- To remove the existing data requirements for antimicrobial pesticide chemicals that currently appear in 40 CFR part 161 (see 73 FR at 59446).
- To amend the table in 40 CFR 158.400(d) by removing the category ''Efficacy of antimicrobial agents'' and all of the entries under that category (see 73 FR at 59431).
- To create a new provision and table to address product performance data for antimicrobial agents in 40 CFR 158.2220 (see 73 FR at 59432).

EPA is therefore also presenting an alternate proposal to amend the table that proposed to consolidate the product performance data requirements for antimicrobials in proposed 40 CFR 158.2220 to include an entry in the proposed data table at 40 CFR 158.2220(c) to specify that efficacy data are required for prion-related products.

In summary, EPA is proposing to more clearly specify that efficacy data are required for prion-related products by either:

- Inserting a new entry in the data tables that are currently found in 40 CFR 158.400 and 40 CFR 161.640.
- If the 2008 proposal concerning proposed 40 CFR 158.2220 has been finalized, by inserting a new entry in the data table that was proposed to be included in 40 CFR 158.2220.

IV. Draft Test Guidelines

EPA is also announcing the availability of draft test guidelines for public review and comment that the Agency intends to include in the OCSPP harmonized test guidelines described in Unit II.D., as part of the 810 Series of Product Performance Test Guidelines. Specifically, the draft 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. 2). The guidelines for products with prion-related claims are designed to provide 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. 3), 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. The SAP provided comments on the draft guidance document on June 29, 2009 (Ref. 4). EPA has considered the SAP's recommendations and incorporated changes, as appropriate (Ref. 5). In addition, the draft test guidelines underwent interagency review in 2010.

With this document, EPA is providing an opportunity for public review and comment on the revised draft test guidelines.

V. FIFRA Review Requirements

In accordance with FIFRA sections 25(a), 25(d), and 21(b), the Agency submitted a draft of this proposed rule to the Committee on Agriculture in the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry in the United States Senate, the Secretary of Agriculture, the FIFRA Scientific Advisory Panel (SAP), and the Secretary of Health and Human Services. The SAP and the Secretaries of Agriculture and Health and Human Services waived review of this proposed rule.

VI. Statutory and Executive Order Reviews

This action only proposes to amend an existing regulation to include more specificity regarding an existing efficacy data requirement for products intending to make prion-related claims. It does not otherwise propose to amend or impose any other requirements. The proposed rule will not otherwise involve any significant policy or legal issues, and will not impact existing costs. As such, the Office of Management and Budget (OMB) has determined that this is not a ''significant regulatory action'' under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993) and this action is therefore not subject to review under Executive Orders 12866 and 13563, entitled *Improving Regulation and Regulatory Review* (76 FR 3821, January 21, 2011).

Nor does it impose or change any information collection burden that requires additional review by OMB under the provisions of the Paperwork Reduction Act (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 in to establish a tolerance or an exemption from the requirement to have a tolerance currently approved under 2070–0024 (EPA ICR No. 0276); (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); and (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.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this proposed rule does not have a significant adverse economic impact on a substantial number of small entities. The proposed amendment does not change existing impacts. 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. EPA solicits comments specifically about potential small business impacts.

State, local, and tribal governments are rarely pesticide applicants or registrants, so this proposed rule is not expected to affect these governments. Accordingly, pursuant to Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538), EPA has determined that this action is not subject to the requirements in sections 202 and 205 because it 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 for the private sector in any 1 year. In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. For the same reasons, EPA has determined that this proposed rule does not have ''federalism implications'' as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), because it would 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 the Order. Thus, Executive Order 13132 does not apply to this proposed rule. Nor does it have ''tribal implications'' as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 22951, November 9, 2000). EPA is not aware of any tribal governments which are pesticide registrants. Thus, Executive Order 13175 does not apply to this action.

Since this action is not economically significant under Executive Order 12866, it is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), and Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001).

This action does not involve technical standards that would require the consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

This action does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, this action does not involve special consideration of environmental justice related issues as specified in Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

VII. References

As indicated under **ADDRESSES**, a docket has been established for this rulemaking under docket ID number EPA–HQ–OPP–2010–0427. 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 technical contact 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. 2010. Product Performance Test Guidelines, Series 810, Draft OCSPP No. 810.2700, entitled ''Products with Prion Related Claims.'' Draft dated November 12, 2010.
3. U.S. Environmental Protection Agency. 2009. Product Performance Test Guidelines, Series 810, Draft OCSPP No. 810.2400, entitled ''Products with Prion Related Claims.'' Draft dated February 23, 2009.
4. 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.*
5. 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.

List of Subjects in 40 CFR Parts 158 and 161

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

Dated: October 31, 2011.

Lisa P. Jackson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 158—[AMENDED]

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

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

2. 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.

* * * * *

(d) * * *

TABLE—PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline No.	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	.....
*	*	*	*	*	*	*	*	*	*	*	*	*	

* * * * *

3. As proposed at 73 FR 59432, October 8, 2008, § 158.2220(c) is further amended by adding a new entry at the end of the table to read as follows:

§ 158.2220 Product performance.

* * * * *

(c) * * *

TABLE—ANTIMICROBIAL PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline No.	Data requirement	All use patterns	Test substance
*	*	*	*
810.2700	Products with prion-related claims	R	EP.

PART 161—[AMENDED]

4. The authority citation for part 161 is revised to read as follows:

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

5. In § 161.640(a), 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:

§ 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 anti-microbial agent													
*		*		*		*		*		*		*	
Products with prion-related claims.	.....	.....	.....	.....	.....	.....	.....	.....	.....	R	.....	EP *	810.2700
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