contact Ms. Cheryl Vetter, Air Quality Policy Division, Office of Air Quality Planning and Standards (C504–03), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–4391; fax number: (919) 541–5509; e-mail address: *vetter.cheryl@mailto:epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

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

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. 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. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), U.S. EPA, Research Triangle Park, NC 27711, Attention Docket ID No. EPA–HQ–OAR–2010–1033.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- 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.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this notice will also be available on the World Wide Web (WWW). Following signature, a copy of this notice will be posted in the regulations and standards section of our EPA New Source review home page located at *http://www.epa.gov/nsr.*

Dated: January 20, 2011.

Mary E. Henigin,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2011–1637 Filed 1–25–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA–HQ–OPP–2010–0427; FRL–8850–4]

RIN 2070–AJ26

Declaration of Prion as a Pest Under FIFRA and Amendment of EPA's Regulatory Definition of Pests To Include Prion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes 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 currently considers 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 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 proposed rule would codify the Agency's current interpretation of FIFRA, and provides interested parties the opportunity to comment about how it is adding prion to the list of pests in the regulatory definition of pest. This amendment, together with the formal declaration that a prion is a pest, will eliminate any confusion about the status of prion-related products under FIFRA. Codifying the Agency's current interpretation of FIFRA will not change the manner in which EPA currently regulates prion-related products under FIFRA sections 3, 24(c) and 18. 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.

DATES: Comments must be received on or before March 28, 2011.

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 e-mail. The regulations.gov website 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 e-mail comment directly to EPA without going through regulations.gov, your e-mail 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, 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; e-mail 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).
- Mortician services (NAICS code 812210).
- Manufacturers of medical tissue devices of human and animal origin (NAICS code undetermined).
- Manufacturers of other human cellular and tissue products (NAICS code undetermined).
- Organ banks, body (NAICS code 621991).
- Plasma, blood, merchant wholesalers (NAICS code 424210).

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 e-mail. 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 action is the Agency taking?

EPA has decided that under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) a prion is considered to be a pest, and proposes to declare a prion to be a pest and to explicitly include it in the lists of pests in 40 CFR 152.5. These actions would affirm the Agency's authority to regulate products distributed or sold for the purpose of reducing the infectivity of prions on inanimate surfaces (*i.e.,* prion-related products). Prion-related products are currently regulated under FIFRA and subject to all requirements and provisions of the Act based on EPA's September 10, 2003 decision 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 proposal ensures that the regulatory definition reflects the Agency's authority to regulate products distributed or sold for the purpose of reducing the infectivity of prions on inanimate surfaces (*i.e.,* 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 or exempted under FIFRA sections 3, 24(c), or 18 before such products may be distributed or sold in the United States.

Note that not all prions and prion-related products are affected by the proposed rule. Firstly, EPA's regulations at 40 CFR 152.5(d) exclude pests "* * * in or on living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs * * * and cosmetics." Therefore, the proposed rule would not apply to those uses of prion-related products. Secondly, the definition of "pesticide" in FIFRA section 2(u) excludes new animal drugs and liquid chemical sterilants intended for use on a critical or semi-critical device. Accordingly, products which fall into those categories would not be covered by the proposed rule.

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).

III. Prion as a Pest Under FIFRA

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 (TSEs). 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 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. Legal/Regulatory Background

Under section 25(c)(1) of FIFRA, the Administrator, after notice and opportunity for hearing, is authorized "to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment." Therefore, the Agency has the authority to decide whether or not a prion should be considered to be a pest under FIFRA and whether to issue a regulation implementing that decision.

On September 10, 2003, the EPA decided that a prion should be considered to be a "pest" under FIFRA and that products intended to inactivate prions (*i.e.*, "prion-related products") should be regulated under FIFRA (Ref. 1). This decision was made partly in connection with the widespread occurrence of chronic wasting disease (CWD) among deer and elk in a number of states, particularly in the Rocky Mountain region. Although CWD had been endemic to that region for a long time, concerns were growing inside and outside of EPA as to how to prevent or minimize the movement of what is believed to be the causative agent for CWD—prions—through the environment.

At the same time, EPA was receiving inquiries from states about obtaining FIFRA section 18 exemptions to allow use of a disinfectant against prions on inanimate surfaces in government and commercial laboratories. EPA was also aware that the World Health Organization (WHO) recommended the use of sodium hydroxide or sodium hypochlorite for treating surfaces potentially contaminated with prions even though those chemicals were not registered by EPA for that specific purpose. Subsequent to the September 2003 decision, EPA has granted a total of 19 quarantine exemptions under FIFRA section 18 to numerous states (California, Colorado, Maine, Minnesota, Montana, North Dakota, South Dakota, Utah, and Wyoming) and the U.S. Department of Agriculture (USDA) for the use of a commercial aqueous acid phenolic product, Environ LpH, for treatment on hard, nonporous surfaces in government and commercial laboratories contaminated with CWD and other kinds of prions.

Other Federal agencies are responsible for implementing controls to prevent the spread of prion diseases to animals and humans. For example, to eliminate scrapie within the United States, USDA's Animal and Plant Health Inspection Service (APHIS) administers the national scrapie eradication program (9 CFR parts 54 and 79). APHIS also intends to establish a herd certification program to prevent and control CWD from farmed or captive cervids in the United States (9 CFR parts 55 and 81). In addition, APHIS regulates the importation of animals and animal products into the United States to guard against the introduction of various animal diseases, including BSE (9 CFR parts 92, 93, 94, and 95). To prevent the spread of BSE through animal feed, the Food & Drug Administration (FDA) prohibits the use of most mammalian protein in the manufacture of animal feed used for ruminants and prohibits high risk cattle materials from all animal feed (21 CFR part 589). To prevent potential human exposure to the BSE agent, USDA's Food Safety and Inspection Service prohibits for use as human food cattle materials that could potentially contain the BSE agent (9 CFR 310.22). FDA has also issued an interim final rule (69 FR 42256, July 14, 2004) prohibiting the use of certain cattle materials in human food and cosmetics to address the potential risk of BSE (21 CFR 189.5 and 700.27).

C. EPA's Interpretation of FIFRA

1. *Applicable FIFRA provisions.* FIFRA section 25(c)(1) authorizes the Administrator "to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment." FIFRA section 2(t) defines a pest, in part, as "* * * any other form of terrestrial or aquatic plant or animal life or virus, bacteria or other micro-organism * * * which the Administrator declares to be a pest under section 25(c)(1)." These FIFRA sections provide EPA the authority to declare an entity to be a "pest" if it meets these statutory provisions.

2. *EPA's interpretation of FIFRA.* EPA's decision to declare a prion to be a pest under FIFRA rests on its statutory interpretation of FIFRA sections 25(c)(1) and 2(t). EPA believes that Congress intended that the phrases "any other form of plant or animal life" and "other micro-organism" be broadly interpreted to include biological entities that are injurious to humans or the environment. The following points provide EPA's rationale for this interpretation.

- In FIFRA, Congress has over the years used the term "other micro-organism" more broadly than most microbiologists currently would define the term because, as used in FIFRA, the term "micro-organism" includes viruses, which many microbiologists do not consider to be microorganisms. Therefore, the term "micro-organism," as currently defined by many microbiologists, is narrower than the potential scope of the term "other micro-organism" in FIFRA.
- As used in FIFRA, the term "other micro-organism" includes entities other than viruses and bacteria, but it is unclear which entities. It is reasonable to assume that it includes those entities that most microbiologists currently recognize as microorganisms (*i.e.*, microfungi, yeasts, and protists).

Because the statutory language explicitly includes viruses among micro-organisms in the definition of "pest," the term "other micro-organism" in its statutory context reasonably may be interpreted to include some other entities that many microbiologists may not categorize as microorganisms.

• Today, microbiologists do not generally classify viruses as microorganisms because they are not alive (*i.e.*, they cannot reproduce sexually or asexually, grow or perform self-maintenance). Therefore, the term "other micro-organism" as used in FIFRA appears broad enough to include some entities that are not alive.

• Congress' rationale for including viruses within the FIFRA definition of "pest" is not known as there is no available legislative history on this issue. However, it is reasonable to infer that Congress included viruses within the FIFRA definition of "pest" and within the scope of the meaning of "micro-organism" because viruses share important characteristics of other pests. The characteristics of a virus that make it resemble a micro-organism in the context of "pest" are pathogenicity, infectivity, transmissibility, the ability to increase in number, and the ability to evolve. EPA believes that Congress intended the terms "pest" and "other micro-organism" as used in FIFRA to be broadly inclusive.

• One entity that shares the characteristics of pathogenicity, infectivity, transmissibility, the ability to increase in number, and the ability to evolve (but which, like viruses, is not alive) is the prion. A prion is an infectious agent occurring in the tissues of animals that is widely, though not universally, believed to be composed of an abnormal (misfolded) protein without nucleic acid. Prions are also unquestionably injurious to the health of humans and other animals. They cause TSE diseases that attack the nervous system, inflict irreversible damage, and are always fatal to infected animals and humans. Once introduced into an animal or human host, prions can induce the formation of new prions in the animal or human host. Prions are considered among the most difficult of all biological entities to mitigate and few methods are available for effectively doing so. Moreover, current test methods cannot demonstrate complete destruction or inactivation of prions. For these reasons, EPA believes that the public needs assurance of the safety and efficacy of products intended to reduce the infectivity of prions.

• Congress expressly included "prion" within another statute's definition of "pest," namely in the Animal Health Protection Act of 2002.

For these reasons, EPA concluded that a prion is appropriately included in the phrase "other micro-organism." Because prions are also severely injurious to human and animal health, EPA has also concluded that a prion is appropriately included in the FIFRA definition of "pest."

D. EPA's Prion Science Evaluation and Efficacy Test Guidance Documents

To assure that this rulemaking is based on the best available scientific information, EPA reviewed and summarized the most relevant scientific studies and publications related to the issue of whether a prion is a pest in a "white paper" (Ref. 2). EPA presented the draft white paper to the FIFRA Scientific Advisory Panel (SAP) for peer review and comment on March 31 and April 1, 2009. The SAP provided comments to EPA on the draft white paper on June 29, 2009 (Ref. 3). EPA subsequently responded to the SAP's comments (Ref. 4) and made revisions to the white paper in response to the SAP comments (Ref. 5). All of these referenced documents are available in the docket for this declaration and proposed rule.

IV. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA has submitted a draft of the proposed rule to the FIFRA SAP, the Secretary of Agriculture (USDA), and appropriate Congressional Committees. In addition, pursuant to FIFRA section 21(b), EPA submitted a draft of the proposed rule to the Secretary of Health and Human Services (HHS).

The FIFRA SAP waived its review of this proposal on June 1, 2010, because the significant scientific issues involved have already been reviewed by the SAP and additional review is not necessary. A copy of this waiver is available in the docket.

As required by FIFRA section 25(a), the written comments on the draft proposal received from USDA and HHS, along with EPA responses, are available in the docket. EPA addressed these comments as part of the interagency review process under Executive Order 12866, and changes made to the proposed rule in response to all comments received during that interagency review are documented in the docket as required by Executive Order 12866.

V. Statutory and Executive Order Reviews

A. Regulatory Review

Pursuant to Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this proposed rule is a "significant regulatory action" because this action might raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this proposed rulemaking to OMB for review under Executive Order 12866. Any changes made in response to OMB comments have been documented in the docket for this rulemaking as required by the Executive Order.

EPA has prepared an economic analysis of the potential costs associated with this proposed action, entitled *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)* (Ref. 8). A copy of this document is available in the docket for this rulemaking, and is briefly summarized here.

The Economic Analysis (EA) presents the Agency's assessment of the potential costs and benefits expected to result from the proposed rule. In terms of benefits, the proposed 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 the proposed rule per registration action range from $424,000 to $4.72 million.

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

The EA estimates that three firms may seek registrations for major new use products in the first year. If all uses are high exposure (*e.g.*, indirect food uses), 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 dollars 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 proposed 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.

The EA evaluates the impacts of the data required to support the registration of a prion-related product, specifically the need for a product performance test that will measure the ability of an individual product to reduce the infectivity of prions. The Agency has developed draft test guidelines for prions which will ensure that the Agency receives the data needed to make objective and reliable determinations as to whether a prion-related product meets the Agency's efficacy data requirements for registration. Providing clear guidance on EPA's efficacy data requirements for prion-related products will benefit registrants by enabling them to submit relevant, correct and complete data submissions in support of applications for registration to the Agency.

One unintended consequence of using products approved for use under FIFRA section 18 exemptions is that at least one state, California, requires that such products be applied only by certified applicators. EPA further understands, however, that California has no such requirement for pesticide products that are registered under FIFRA section 3 or 24(c) that are not classified for restricted use. Hence, laboratories in California that use prion-related products registered under section 3 or 24(c) would not be subject to a certified applicator requirement. The initial cost of obtaining the certified applicator's license in California is $140, and the renewal fee is $60 every 2 years (*see http://www.cdpr.ca.gov/docs/license/qac.htm*). In addition, 20 hours of continuing education is required to obtain renewal. If a similar requirement is imposed by other states, the cost to laboratories for obtaining applicator licenses would probably be about the same. No such cost is associated with products registered under section 3 or 24(c).

B. Paperwork Activities

The information collection requirements, *i.e.,* the paperwork collection activities, contained in this proposal are already approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* Specifically, the activities contained in this proposed rule are already addressed in the following information collection requests (ICRs):

1. The activities associated with the establishment of a tolerance are 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 are currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277).

3. The activities associated with the generation of data in response to a Data-Call-In issued subsequent to registration (*e.g.,* as part of the review of an existing registration), are currently approved under OMB Control No. 2070–0174 (EPA ICR No. 2288).

The existing ICRs cover the paperwork activities contained in this proposal because the activities already occur as part of existing program activities. These program activities are an integral part of the Agency pesticide program and the corresponding ICRs are regularly renewed. Although this proposal involves already approved activities, the estimated frequency of those activities may increase as a result of this proposal. The total estimated average annual public reporting burden currently approved by OMB for these various activities ranges from approximately 8 hours to 3,000 hours per respondent, depending on the activity and other factors surrounding the particular pesticide product. According to EPA's EA for this proposed rule (Ref. 8), using the estimate of three major new use product registrations in the first year, the additional registration of three antimicrobial products making prion-related claims will result in an increase in new registration applications for the Agency from 140 to 143 and an increase in tolerance petitions of from 64 to 67. The increase in paperwork burden for the registrant will be nearly $38,000 (600 hours for three registrations) for registration activities and a little more than $423,000 (5,200 hours for three registrations) for paperwork for tolerance petitions (Ref. 8).

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations, after appearing in the preamble of the final rule, are listed in 40 CFR part 9 and 48 CFR chapter 15, and included on the related collection instrument (*e.g.,* form or survey).

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments are requested on the Agency's need for this information, the accuracy of the burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments to EPA as part of your overall comments on this proposed action in the manner specified under **ADDRESSES**. In the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposed rule.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* after considering the potential economic impacts of this proposed rule on small entities, I hereby certify that this proposed rule would not have a significant adverse economic impact on a substantial number of small

entities. This determination is based on the Agency's economic analysis (Ref. 8), and is briefly summarized here.

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's proposed 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 (in this case based on maximum number of employees or sales for small businesses in each industry sector, as defined by a 6-digit NAICS code); (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; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Since the regulated community does not include small governmental jurisdictions or small not-for-profit organizations, the analysis focuses on small businesses.

According to the Agency's economic analysis (Ref. 8), only three firms are expected to apply for registrations of prion-related products. One of these firms is known to be a large firm. Given that approximately 79% of the firms in the antimicrobial industry are small firms, it is possible that any or all of the remaining two other firms could qualify as a small entity under the SBA definition.

The incremental costs of the proposed rule could represent from 2% to 11% of the average annual revenues of a small firm. In general, the Agency does not believe that prion-related products are an important market segment for sodium hydroxide or sodium hypochlorite producing firms and does not anticipate a large number of product registrations beyond the first year the final rule would take effect. If small entities apply to register products for prion control, they would likely pursue a registration where they could likely cite a substantial amount of data and not incur 100% of the initial costs of testing (Ref. 8).

EPA continues to be interested in the potential impacts of this proposed rule on small entities and welcomes comments on issues related to such impacts.

D. Unfunded Mandates

This action does not contain any Federal mandates for State, local, or tribal governments or the private sector under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538. EPA has determined that this regulatory action will not result in annual expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector. As described in Unit IV.A., the incremental costs for the proposed rule are estimated from $424,000 to $4.72 million. Since State, local, and tribal governments are rarely pesticide applicants, the proposed rule is not expected to significantly or uniquely affect small governments. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect on small governments. Accordingly, this action is not subject to the requirements of sections 202, 203 or 205 of UMRA.

E. Federalism Implications

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this proposed 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 the Order. As indicated previously, instances where a state is a registrant are extremely rare. Therefore, this proposed rule may seldom affect a state government. Thus, Executive Order 13132 does not apply to this proposed rule.

In the spirit of the Order, and consistent with EPA policy to promote communications between the Agency and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Tribal Implications

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this proposed rule does not have "tribal implications" 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, as specified in the Order. As indicated previously, at present, no tribal governments hold, or have applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this proposed rule.

In the spirit of the Order, and consistent with EPA policy to promote communications between the Agency and State and local governments, EPA specifically solicits comment on this proposed rule from tribal officials.

G. Children's Health

EPA interprets Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (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 Executive Order 13045 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, and it is not designated as an "economically significant" regulatory action as defined by Executive Order 12866 (*see* Unit V.A.). To the contrary, this action will provide added protection for children from pesticide risk.

H. Energy Effects

This action is not a "significant energy action" as defined in Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because it is not likely to have an effect on the supply, distribution, or use of energy as described in the Order.

I. Technical Standards

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (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 impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, and sampling procedures) 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 propose to require any technical standards that would require Agency consideration of voluntary consensus standards. This action proposes the types of data to be required to support the registration of antimicrobial pesticide products with prion-related claims but does not propose to require specific methods or standards to generate those data.

The Agency invites comment on its conclusion regarding the applicability of

voluntary consensus standards to this proposed rulemaking.

J. Environmental Justice

This proposed rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency does not need to consider environmental justice-related issues.

VI. 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 in developing this proposed rule, 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. 2009. "Scientific Information Concerning the Issue of Whether Prions Are a 'Pest' under the Federal Insecticide, Fungicide, and Rodenticide Act." Draft dated February 23, 2009.

3. 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, PhD, Director, Office of Pesticide Programs. June 29, 2009. See *http://www.epa.gov/scipoly/sap/meetings/2009/march/033109panelmembers.html.*

4. 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.

5. U.S. Environmental Protection Agency. 2010. Scientific Information Concerning the Issue of Whether A Prion Is a "Pest" under the Federal Insecticide, Fungicide, and Rodenticide Act. February 17, 2010.

6. U.S. Environmental Protection Agency. 2009. Product Performance Test Guidelines OPPTS 810.XXXX Products with Prion Related Claims. Draft dated February 23, 2009.

7. U.S. Environmental Protection Agency. 2009. Product Performance Test Guidelines OPPTS 810.XXXX Products with Prion Related Claims. Draft dated December 8, 2009.

8. U.S. Environmental Protection Agency. 2010. Economic Analysis of the Notice of Proposed Rulemaking Concerning that Status of a Prion as a Pest under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). February 17, 2010.

List of Subjects in 40 CFR Part 152

Environmental protection, Antimicrobial pesticides, Prion.

Dated: January 14, 2011.

Lisa P. Jackson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be 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. Section 152.5 is amended by revising 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)).

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