



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

[EPA-HQ-OPP-2010-0785; FRL-9325-5]

RIN 2070-AJ76

Protections for Subjects in Human Research Involving Pesticides; Notification of Submission to the Secretary of Agriculture

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of submission to the Secretary of Agriculture.

SUMMARY: This document notifies the public that the Administrator of EPA has forwarded to the Secretary of the United States Department of Agriculture (USDA) a draft final rule as required by section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0785. All documents in the docket are listed in the docket index available in <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 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 Docket Facility is open 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: Kelly Sherman, Immediate Office of the Director (7501P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460-0001; telephone number: (703) 305-8401; email address: *sherman.kelly@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general. It simply announces the submission of a draft final rule to the Secretary of USDA and does not otherwise affect any specific entities. This action may, however, be of particular interest to pesticide registrants (NAICS code 325320) who sponsor or conduct human research for pesticides, and to other entities that sponsor or conduct human research for pesticides (NAICS code 541710). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What Action is EPA Taking?

As described in the Agency's semi-annual Regulatory Agenda, the draft final rule would take final action with regard to the proposed rule issued on February 2, 2011 (76 FR 5735). The amendments would make no changes to the Common Rule or EPA's codification of the Common Rule. EPA proposed these amendments as a result of a settlement agreement.

Section 25(a)(2)(B) of FIFRA requires the EPA Administrator to provide the Secretary of USDA with a copy of any draft final rule at least 30 days before signing it in final form for publication in the **Federal Register**. The draft final rule is not available to the public until after it has been signed by EPA. If the Secretary of USDA comments in writing regarding the draft final rule within 15 days after receiving it, the EPA Administrator shall include in the final rule, when published in the **Federal Register**, the comments of the Secretary of USDA, if requested by the Secretary of USDA, and the EPA Administrator's response to those comments. If the Secretary of USDA does not comment in writing within 15 days after receiving the draft final rule, the EPA Administrator may sign the final rule for publication in the **Federal Register** any time after the 15-day period.

III. Do Any Statutory and Executive Order Reviews Apply to this Notification?

No. This document is not a rule. It is merely a notification of submission to the Secretary of USDA. As such, none of the regulatory assessment requirements apply to this document.

IV. Will this Notification be Subject to the Congressional Review Act?

No. This action is not a rule for purposes of the Congressional Review Act (CRA), 5 U.S.C. 804(3), and will not be submitted to Congress and the Comptroller General. EPA will submit the final rule to Congress and the Comptroller General as required by CRA.

List of Subjects in 40 CFR Part 26

Environmental protection, Human research, Pesticides.

Dated: November 4, 2011.

Steven Bradbury,
Director, Office of Pesticide Programs.

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