ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

[EPA–HQ–OPP–2003–0132; FRL–8071–6]

RIN 2070–AD57

Protections for Subjects in Human Research; Nursing Women

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to explicitly ban research for pesticides involving intentional exposure of human subjects who are nursing women, and therefore providing protection to any nursing infants who may also be exposed. The direct final rule also prohibits EPA reliance in actions under the pesticide laws on research involving intentional exposure of nursing women.

DATES: This direct final rule is effective on August 22, 2006 without further notice, unless EPA receives adverse comment on or before July 24, 2006. If EPA receives adverse comments to the direct final rule, EPA will publish a timely withdrawal document in the **Federal Register** informing the public that this direct final rule rule will not take effect.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2003–0132, 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'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–2003–0132. 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. 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 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: EPA has established a docket for this action under docket ID number EPA–HQ–OPP–2003–0132. All documents in the docket are listed in the index for the docket. Although listed in the docket 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 available through the electronic docket and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Public Regulatory Docket, in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation for 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: William L. Jordan, Office of Pesticide Programs (7501P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1049; fax number: (703) 308–4776; e-mail address: *jordan.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What Does this Direct Final Rule Do?

With this direct final rule, EPA clarifies the protections for subjects of ''third-party'' human research (i.e., research that is not conducted or supported by either EPA or by another Federal Department or Agency under the ''Common Rule'') by prohibiting new research involving intentional exposure of nursing women, intended for submission to EPA under the pesticide laws, thereby providing protection to any nursing infants who may also be exposed. This direct final rule also prohibits any EPA research involving intentional exposure of human subjects who are nursing women to pesticides or any other substances. (Research conducted by EPA is referred to as ''first-party'' research, and ''second-party'' research refers to research supported by EPA but performed by others. ''Third-party'' research refers to any research that is not ''first-party'' or ''second-party'' research.) Finally, this rule prohibits EPA reliance, in actions under the pesticide laws, on human research involving intentional exposure of nursing women as subjects.

B. Legal Authority

This direct final rule is authorized under provisions of the following statutes that EPA administers: Section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136–136y), which authorizes the Administrator to ''prescribe regulations to carry out the purposes of [FIFRA],'' and section 408(e)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a). FFDCA authorizes the Administrator to issue a regulation establishing ''general procedures and requirements to implement [Section 408].'' In addition, the portions of this regulation supplementing EPA's codification of the Common Rule regarding first- and second-party research are authorized pursuant to 5 U.S.C. 301 and 42 U.S.C. 300v–1(b).

This direct final rule amends the recently promulgated ''Protections for Subjects in Human Research Rule'' (hereinafter referred to as the ''January 2006 rule'') to extend critical protections for human research subjects contained in that rule to nursing women and their nursing children. The January 2006 rule published in the **Federal Register** on February 6, 2006 (71 FR 6138) (FRL–7759–8). EPA is publishing this direct final rule without prior proposal because the Agency believes that these amendments are non-controversial and does not expect to receive adverse comments. Nevertheless, EPA is also publishing a separate document in the ''Proposed Rules'' section of this issue of the **Federal Register** that serves as the proposal to extend these critical protections for subjects of human

research to nursing women and their nursing children, in the event that adverse comments are submitted to EPA on or before July 24, 2006.

This direct final rule is effective on August 22, 2006 without further notice, unless EPA receives comments that are adverse to the direct final rule on or before July 24, 2006. If EPA receives comments that are adverse to this direct final rule, the Agency will publish a timely withdrawal document in the **Federal Register** informing the public that the direct final rule will not take effect on August 22, 2006. EPA will then address all public comments received in a subsequent final rule based on the proposed rule that is published in the ''Proposed Rules'' section of this issue of the **Federal Register**. The Agency will not institute a second comment period on this action. Any parties interested in commenting must do so at this time and must submit comments by the date indicated in this unit and in the proposed rule.

C. Does this Action Apply to Me?

You may be potentially affected by this action if you conduct human research on substances regulated by EPA. Potentially affected entities may include, but are not limited to, entities that conduct or sponsor research involving intentional exposure of human subjects that may be submitted to EPA under FIFRA or FFDCA. Although EPA has in the past received such third-party research from pesticide registrants, other entities could submit such information to EPA.

• Pesticide and other Agricultural Chemical Manufacturing (NAICS code 325320).

This listing is not intended to be exhaustive, but rather provides a guide 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions of 40 CFR part 26. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

D. How Can I Access Electronic Copies of this Document and Other Related Information?

You may access an electronic copy of this **Federal Register** document and the associated electronic docket at *http://www.regulations.gov*, or you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. A frequently updated electronic version of the Code of Federal Regulations (CFR) is available at *http://www.gpoaccess.gov/ecfr*.

II. EPA's January 2006 Promulgation of Protections for Subjects of Human Research

On January 26, 2006, EPA issued a final rule significantly strengthening and expanding the protections for subjects of human research. For ''third-party'' human research (i.e., research that is not conducted or supported by either EPA or by another Federal Department or Agency under the Common Rule), that rule:

1. Prohibited new research involving intentional exposure of pregnant women or children, intended for submission to EPA under the pesticide laws.

2. Extended the provisions of the Federal Policy for the Protection of Human Subjects of Research (the ''Common Rule'') to other human research involving intentional exposure of non-pregnant adults, intended for submission to EPA under the pesticide laws.

3. Required submission to EPA of protocols and related information about covered human research before it is initiated.

4. Established an independent Human Studies Review Board to review both proposals for new research and reports of covered human research on which EPA proposes to rely under the pesticide laws.

The January 2006 rule also contained other, similar requirements for first- and second-party research, as well as standards to guide EPA decisionmaking under the pesticide laws involving reliance on the results of completed intentional dosing human research.

III. Protections for Children Potentially Exposed Through Nursing Women Who Are Subjects in Human Research

In the January 2006 rule, EPA provided additional protections for children, to prohibit their being intentionally exposed to test materials through human research. The Agency believed that it had achieved this goal by establishing a prohibition against the use of children as subjects in certain types of research involving intentional exposure of subjects. Since promulgation of the January 2006 rule, however, the Agency has been asked whether the final rule prohibits investigators from conducting, or EPA from relying on, research involving intentional exposure of nursing women, since use of nursing women as subjects of research could potentially result in exposure of nursing infants to the test material in nursing women's breast milk.

The Agency notes that it has not conducted or supported intentional dosing studies targeted at nursing women and has no intention to do so in the future. Moreover, under the January 2006 rule, if, in accordance with 40 CFR 26.1125, a third-party researcher submitted to EPA a proposal to perform such research, EPA would not approve the proposal. The Agency has concluded that such research should never be performed because of the potential that it might result in exposure of nursing children. Accordingly, EPA is amending the January 2006 rule to clarify that the prohibitions in the January 2006 rule against conduct of new research involving intentional exposure of pregnant women and children, and the prohibition of the Agency's reliance on completed research involving intentional exposure of pregnant women or children, apply as well to research involving intentional exposure of nursing women. The rule explicitly prohibits research involving intentional exposure of nursing women. EPA would consider a woman to be nursing if she is providing her breast milk to a child either during or after the research when the test material could be detected in her breast milk. (For purposes of applying the rule to research conducted after the effective date of this action, an investigator could document compliance by obtaining a statement from a female subject that she is not providing and does not intend to provide her breast milk to a child during the research and for a period of time after the research ends during which the test material could reasonably be detected in her breast milk. The Agency does not intend, however, to prohibit research involving intentional exposure of a woman as a research subject simply because at some indefinite, future time the woman hopes to breast-feed a child.)

In sum, the Agency believes that the kinds of explicit protections for children and pregnant women established by the January 2006 rule are equally appropriate for nursing women. Data indicate that some pesticides and other environmental substances pass into breast milk, but adequate data do not exist to characterize the fate of all substances that might be used in human research covered by the January 2006 rule. Therefore, consistent with the intent of the January 2006 rule to protect

children from exposure to test materials through intentional dosing studies, EPA is reinforcing the protection for children by prohibiting the following:

1. New research involving intentional exposure of nursing women conducted or supported by EPA.

2. New research involving intentional exposure of nursing women conducted by third-party investigators who intend to submit the results to EPA under the pesticide laws.

3. Reliance by EPA in its actions under the pesticide laws on research involving intentional exposure of nursing women.

(EPA notes that the absence of information about the nursing status of female subjects in a completed study does not justify application of the prohibition in § 26.1703.)

IV. FIFRA Review Procedures for the Direct Final Rule

FIFRA section 25(a)(2)(B) provides: ''[a]t least 30 days prior to signing any regulation in final form for publication in the **Federal Register**, the Administrator shall provide the Secretary of Agriculture a copy of such regulation.'' This section also authorizes the Secretary to waive the opportunity to review and comment on final regulations. FIFRA section 25(d)(1) states that ''[t]he Administrator shall submit to an advisory panel for comment [the] final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture . . .'' This subsection also authorizes the FIFRA Scientific Advisory Panel (SAP) to waive the opportunity for review. Both, the FIFRA SAP and the U.S. Department of Agriculture (USDA) have waived the opportunity under FIFRA to review the direct final rule.

In addition, FIFRA section 25(a)(3) states that ''[a]t such time as the Administrator is required under paragraph (2) to provide the Secretary of Agriculture with . . . a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture in the House of Representatives, and the Committee on Agriculture, Nutrition, and Forestry in the United States Senate.'' Because USDA waived review under FIFRA section 25(a)(2)(B), EPA is not required to furnish a copy of the final regulations to the specified committees 30 days prior to signature of the direct final rule.

V. Statutory and Executive Order Reviews

A. Executive Order 12866

Under 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 direct final rule is not a ''significant regulatory action'' under section 3(f) of the Executive Order.

The amendments contained in this rule are not expected to result in a significant increase, if any, to the estimated impacts of the January 2006 rule, which are presented in a document entitled *Economic Analysis of the Human Studies Final Rule* (Economic Analysis), a copy of which is available in the docket for this rule.

Based on the relatively small economic impact of the January 2006 rule, EPA believes that this direct final rule will have a minimal—if any—impact on industry, regardless of the size of the entity.

B. Paperwork Reduction Act

This rule contains no new information collection requirements. Therefore no further analysis, review or OMB approval is required under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. The information collection requirements contained in the January 2006 rule have been approved by OMB under OMB control number 2070–0169 (identified under EPA ICR No. 2195.02). A copy of the approved information collection request document is available in the docket for this rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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 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.

After considering the potential economic impacts of the January 2006 rule on small entities, the Agency concluded pursuant to section 605(b) of RFA that the January 2006 rule did not have a significant adverse economic impact on a substantial number of small entities. EPA has determined that the potential additional impact from this direct final rule, if any, is minimal. For purposes of assessing the impacts of the January 2006 rule on small entities, small entity was defined in accordance with the RFA as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.

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.

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 direct 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 Agency's determination is based on the economic analysis performed for the January 2006 rule, a copy of which is available in the docket for this action.

D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action 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. This rule is expected to result in no more than a minor increase, if any, to the estimated impact of the January 2006 rule. The estimated total costs associated with the January 2006 rule are approximately $38,837 per year. Based on historical submissions, EPA has determined that State, local, and tribal governments rarely perform human research intended for submission to EPA under FIFRA or FFDCA. In addition, the direct final rule is not expected to significantly or uniquely affect small governments. Accordingly, this action is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), does not apply to this rule. EPA has determined that 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 the Executive Order. As indicated earlier, instances where a State performs human research intended for submission to EPA under FIFRA or FFDCA are rare. Therefore, this direct

final rule may seldom affect a State government.

F. Executive Order 13175

Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 6, 2000), does not apply to this rule. EPA has determined that this 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 Executive Order. As indicated previously, instances where a tribal government performs human research intended for submission to EPA under FIFRA or FFDCA are extremely rare.

G. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), does not apply to this rule because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866. Furthermore, this rule does not establish an environmental standard that is intended to have a negatively disproportionate effect on children. To the contrary, this action will provide added protections for children with regard to the research covered by the rule.

H. Executive Order 13211

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because this rule does not have any significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

This rule does not impose any technical standards that would require Agency consideration of voluntary consensus standards under section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note) because it does not require specific methods or standards to generate data. The NTTAA 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, sampling procedures) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, with explanations when the Agency decides not to use available and applicable voluntary consensus standards.

J. Executive Order 12898

This 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 is not required to consider environmental justice-related issues.

VI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report that includes a copy of the rule to each House of the Congress and 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**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 26

Environmental protection, Human research subjects, Reporting and recordkeeping requirements.

Dated: June 20, 2006.

Stephen L. Johnson,

Administrator.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 26—[AMENDED]

■ 1. The authority citation for part 26 continues to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); section 201 of Public Law No. 109–54; and 42 U.S.C. 300v–1(b).

■ 2. By revising the heading of subpart B to read as follows:

Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

■ 3. By revising § 26.203 to read as follows:

§ 26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or child.

Notwithstanding any other provision of this part, under no circumstances shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

■ 4. By revising the heading of subpart K to read as follows:

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

■ 5. By revising the heading of subpart L to read as follows:

Subpart L—Prohibition of Third-Party Research for Pesticides Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

■ 6. By revising § 26.1203 to read as follows:

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or support research covered by § 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

■ 7. By revising § 26.1703 to read as follows:

§ 26.1703 Prohibition of reliance on research involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children.

Except as provided in § 26.1706, in actions within the scope of § 26.1701 EPA shall not rely on data from any research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

■ 8. By revising the heading of § 26.1704 to read as follows:

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults conducted before April 7, 2006.

■ 9. By revising the heading of § 26.1705 to read as follows:

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults conducted after April 7, 2006.

[FR Doc. 06–5649 Filed 6–22–06; 8:45 am]
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