(such as for allergy, cough-cold, or pain)''.

(4) The following information shall appear after the subheading ''When using this product'' [in bold type]:

(i) ''[Bullet] increased blood pressure or heart rate can occur, which could lead to more serious problems such as heart attack, stroke, and death. Your risk may increase if you take more frequently or more than the recommended dose.'' [statements shall appear in bold type as the first statements under this subheading]

(ii) ''[Bullet] nervousness, sleeplessness, rapid heart beat, tremor, and seizure may occur. If these symptoms persist or get worse, consult a doctor right away.''

(iii) ''[Bullet] avoid caffeine-containing foods or beverages''.

(iv) ''[Bullet] avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect''.

(5) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in § 341.16(a), (b), (c), and (f).*—(i) The following information shall appear after the subheading ''Asthma alert: Because asthma can be life threatening, see a doctor if you'' [in bold type]:

(A) ''[Bullet] are not better in 60 minutes''.

(B) ''[Bullet] get worse''.

(C) ''[Bullet] need [insert total number of dosage units that equals 150 milligrams] in any day''.

(D) ''[Bullet] use more than [insert total number of dosage units that equals 100 milligrams] a day for more than 3 days a week''.

(E) ''[Bullet] have more than 2 asthma attacks in a week.''

(ii) This ''Asthma alert'' shall appear on any labeling that contains warnings and shall be the first warning statement under the heading ''Warnings''.

(6) *For products containing epinephrine, epinephrine bitartrate, or racepinephrine hydrochloride identified in § 341.16(d), (e), and (g).*—(i) The following information shall appear after the subheading ''Asthma alert: Because asthma can be life threatening, see a doctor if you'' [in bold type]:

(A) ''[Bullet] are not better in 20 minutes''.

(B) ''[Bullet] get worse''.

(C) ''[Bullet] need 12 inhalations in any day''.

(D) ''[Bullet] use more than 9 inhalations a day for more than 3 days a week''.

(E) ''[Bullet] have more than 2 asthma attacks in a week.''

(ii) This ''Asthma alert'' shall appear on any labeling that contains warnings and shall be the first warning statement under the heading ''Warnings''.

(iii) *For products intended for use in a hand-held rubber bulb nebulizer.* The following statement shall also appear after the subheading ''Do not use'' along with the other information in paragraph (c)(1) of this section: ''[bullet] if product is brown in color or cloudy''.

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in § 341.16(a), (b), (c), and (f).*—(i) ''[Bullet] do not exceed dosage'' [sentence appears as first bulleted statement under ''Directions'' and in bold type].

(ii) ''[Bullet] adults and children 12 years of age and over: oral dose is 12.5 to 25 milligrams every 4 hours as needed, not to exceed 150 milligrams in 24 hours''.

(iii) ''[Bullet] children under 12 years of age: ask a doctor''.

(2) *For products containing epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride identified in § 341.16(d), (e), and (g) for use in a hand-held rubber bulb nebulizer.* The ingredient is used in an aqueous solution at a concentration equivalent to 1 percent epinephrine.

(i) ''[Bullet] do not exceed dosage'' [appears as first bulleted statement under ''Directions'' and in bold type].

(ii) ''[Bullet] adults and children 4 years of age and over: 1 to 3 inhalations not more often than every 3 hours. The use of this product by children should be supervised by an adult.''

(iii) ''[Bullet] children under 4 years of age: ask a doctor''.

Dated: June 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–13709 Filed 7–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR 285

[0790–ZA05]

DoD Freedom of Information Act (FOIA) Program (DoDD 5400.7)

AGENCY: Department of Defense.

ACTION: Proposed rule.

SUMMARY: This proposed rule conforms to the requirements of the Electronic Freedom of Information Act Amendments of 1996. It promotes public trust by making the maximum amount of information available to the public, in both hard copy and electronic formats, on the operation and activities of the Department of Defense, consistent with DoD responsibility to protect national security and other DoD interests as provided by applicable law. It also allows a requester to obtain Agency records from the Department of Defense that are available through other public information services without invoking the FOIA.

DATES: Comments must be received on September 12, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. David W. Maier, 703–695–6428

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed regulatory action is not a significant regulatory action, as defined by Executive Order 12866.

Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b))

This proposed regulatory action will not have a significant adverse impact on a substantial number of small entities.

Unfunded Mandates Act of 1995 (Sec. 202, Pub. L. 104–4)

This proposed regulatory action does not contain a Federal mandate that will result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector of $100 million or more in any one year.

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35)

This proposed regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act.

Federalism (Executive Order 13132)

This proposed regulatory action does not have Federalism implications, as set forth in Executive Order 13132. 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.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. Chapter 6)

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule implements the Freedom of Information Act (5 U.S.C. 552), a statute concerning

the release of Federal Government records, and does not economically impact Federal Government relations with the private sector.

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

It has been determined that this rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more and that such rulemaking will not significantly or uniquely affect small governments.

List of Subjects in 32 CFR Part 285

Freedom of information.

Accordingly, 32 CFR part 285 is proposed to be revised to read as follows:

PART 285—DOD FREEDOM OF INFORMATION ACT (FOIA) PROGRAM

Sec.
285.1 Purpose.
285.2 Applicability and scope.
285.3 Policy.
285.4 Responsibilities.
285.5 Information requirements.

Authority: 5 U.S.C. 552.

§ 285.1 Purpose.

This part:

(a) Updates policies and responsibilities for the implementation of the DoD Freedom of Information Act (FOIA) Program under 5 U.S.C. 552.

(b) Continues to delegate authorities and responsibilities for the effective administration of the FOIA program and authorize the publication of DoD 5400.7–R,[1] which is the DoD Regulation on the FOIA Program.

§ 285.2 Applicability and scope.

(a) This part applies to the Office of the Secretary of Defense (OSD), the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereafter referred to collectively as the ''DoD Components'').

(b) National Security Agency/Central Security Service records are subject to this part unless the records are exempt under 50 U.S.C. 402 note of title 50. The records of the Defense Intelligence Agency, the National Reconnaissance Office, and the National Geospatial-Intelligence Agency are also subject to this Part unless the records are exempt under 10 U.S.C. 424.

[1] This Regulation is codified at 32 CFR part 286.

§ 285.3 Policy.

It is DoD policy to:

(a) Promote public trust by making the maximum amount of information available to the public, in both hard copy and electronic formats, on the operation and activities of the Department of Defense, consistent with DoD responsibility to protect national security and other DoD interests as provided by applicable law.

(b) Allow a requester to obtain Agency records from the Department of Defense that are available through other public information services without invoking the FOIA.

(c) Make available, under the procedures established by DoD 5400.7–R, those Agency records that are requested by a member of the public who explicitly or implicitly cites the FOIA.

(d) Answer promptly all other requests for Agency information and records under established procedures and practices.

(e) Release Agency records to the public unless those records are exempt from mandatory disclosure as outlined in 5 U.S.C. 552.

(e) Process requests by individuals for access to records about themselves contained in a Privacy Act system of records under procedures set forth in DoD 5400.11–R [2] and guidance outlined in this part, as amplified by DoD 5400.7–R.

§ 285.4 Responsibilities.

(a) The Director, Administration and Management (DA&M) shall:

(1) Serve as the appellate authority for appeals to decisions of respective Initial Denial Authorities within the OSD, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, select Defense Agencies, and the DoD Field Activities. The DA&M may delegate this responsibility to an appropriate member of the DA&M or Washington Headquarters Services' staff.

(2) Issue a DoD FOIA regulation and other discretionary instructions and guidance to ensure timely and reasonably uniform implementation of the FOIA in the Department of Defense.

(b) The Director, Washington Headquarters Services, under the DA&M, shall:

(1) Direct and administer the DoD FOIA Program to ensure compliance with policies and procedures that govern the administration of the program.

(2) Internally administer the FOIA Program, inclusive of training, for the OSD, the Chairman of the Joint Chiefs of Staff and, as an exception to DoD Directive 5100.3,[3] the Commanders of the Combatant Commands.

(c) The General Counsel of the Department of Defense shall provide uniformity in the legal interpretation of this Part. The General Counsel shall also ensure that affected legal advisors, public affairs officers, and legislative affairs officers are aware of releases through litigation channels which may be of significant public, media, or Congressional interest, or of interest to senior DoD officials.

(d) The Heads of the DoD Components shall:

(1) Internally administer the FOIA Program and publish any instructions that are not prescribed by this Part or by other issuances of the DA&M which have a major impact on the public. The information specified in Section 552(a)(1) of 5 U.S.C. 552 shall be published in accordance with Administrative Instruction 102.[4]

(2) Ensure that respective chains of command, affected legal advisors, public affairs officers and legislative affairs officers are aware of releases through the FOIA, inclusive of releases through litigation channels, which may be of significant public, media, or Congressional interest, or of interest to senior DoD officials.

(3) Conduct training on the provisions of this part, 5 U.S.C. 552, and DoD 5400.7–R for officials and employees who implement the FOIA.

(4) Submit the Annual Report prescribed in Chapter 7 of DoD 5400.7–R.

(5) Make available for public inspection and copying in an appropriate facility or facilities, in accordance with rules published in the **Federal Register**, the records specified in 5 U.S.C. 552(a)(2), unless such records are published and copies are offered for sale. These records shall be made available to the public in hard copy, by computer telecommunications, or other electronic means.

(6) Maintain and make available for public inspection and copying current indices of all (a)(2) records as required by 5 U.S.C. 552(a)(2)

§ 285.5 Information requirements.

The reporting requirements in Chapter 7 of DoD 5400.7–R have been assigned Report Control Symbol DD–DA&M(A)1365.

[2] Copies may be obtained via Internet at *http://www.dtic.mil/whs/directives/corres/pub1.html.*

[3] See footnote 2 to § 285.3(e).

[4] See footnote 2 to § 285.3(e).

Dated: July 7, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13742 Filed 7–12–05; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 155

[OPP–2004–0404; FRL–7718–4]

RIN 2070–AD29

Pesticides; Procedural Regulations for Registration Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Food Quality Protection Act (FQPA) of 1996 amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to require periodic review of pesticide registrations to ensure that over time they continue to meet statutory standards for registration. FIFRA section 3(g) specifies that EPA establish procedural regulations for conducting registration review and the goal of the regulations shall be Agency review of pesticide registrations on a 15–year cycle. This proposal describes the Agency's proposed approach to the registration review program. The proposed regulation is intended to ensure continued review of pesticides using procedures that provide for public participation and transparency in an efficient manner.

DATES: Comments must be received on or before October 11, 2005.

ADDRESSES: Submit your comments, identified by docket ID number OPP–2004–0404, by one of the following methods:

- *Federal eRulemaking Portal*:*http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Agency Website*:*http://www.epa.gov/edocket/*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *E-mail*: Comments may be sent by e-mail to*opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0404.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0404.
- *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0404. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID numberOPP–2004–0404. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket/*, 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 EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, 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 EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public 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. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Vivian Prunier, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–9341; fax number:703–305–5884; e-mail address:*prunier.vivian@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you hold pesticide registrations. Pesticide users or other persons interested in the regulation of the sale, distribution, or use of pesticides may also be interested in this proposed procedural regulation. As such, the Agency is soliciting comments from the public in general. Potentially affected entities may include, but are not limited to:

- Producers of pesticide products (NAICS code 32532)
- Producers of antifoulant paints (NAICS code 32551)
- Producers of antimicrobial pesticides (NAICS code 32561)
- Producers of nitrogen stablilizer products (NAICS code 32531)
- Producers of wood preservatives (NAICS code 32519)

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in proposed § 155.40 of the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.