rubber'' includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

(1) The term ''natural rubber latex'' means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating.

(2) The term ''dry natural rubber'' means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping.

(3) The term ''contacts humans'' means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path; or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient.

(c) Devices containing natural rubber shall be labeled as set forth in paragraphs (d) through (h) of this section. Each required labeling statement shall be prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)).

(d) Devices containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(e) Devices containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling:

''This Product Contains Dry Natural Rubber.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''The Packaging of This Product Contains Dry Natural Rubber.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term ''hypoallergenic'' on their labeling.

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with § 10.30 of this chapter.

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)).

Dated: September 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25728 Filed 9–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2610]

Bureau of Consular Affairs; Visas: Passports and Visas Not Required for Certain Nonimmigrants

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Interim rule with request for comments.

SUMMARY: Section 217 of the Immigration and Nationality Act (INA), as amended, extends the Visa Waiver Pilot Program (VWPP) to nationals of all countries that qualify under the provisions of the Pilot Program and which are designated by the Secretary of State and the Attorney General as countries whose nationals benefit from the waiver of the nonimmigrant B–1/B–2 visa requirement. This interim rule eliminates probationary entry status in the pilot program, designates Ireland (the only country formerly designated as a participating country with probationary status) as a permanent participating country and extends the VWPP to Slovenia.

DATES: This interim rule is effective September 30, 1997. Written comments are invited and must be received on or before October 30, 1997.

ADDRESSES: Written comments may be submitted, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Room L–603C, Department of State, Washington, D.C. 20520–0106.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Department of State, Washington, D.C. 20522–0113 (202) 663–1203.

SUPPLEMENTARY INFORMATION: This interim rule amends Part 41, Title 22 of the Code of Federal Regulations concerning visas for nonimmigrants pursuant to section 217 of the Immigration and Nationality Act, 8 U.S.C. 1187, as amended by Pub. L. 103–415, (108 Stat. 4299, October 25,1994), Pub. L. 103–416, (108 Stat. 4305, October 25, 1994), and Pub. L. 104–208, (110 Stat. 3009–702, September 30, 1996).

Pub. L. 99–603

Section 313 of the Immigration Reform and Control Act of 1986 (IRCA), Pub. L. 99–603, amended the INA by adding a new section 217 (8 U.S.C. 1187). Section 217 provides for a nonimmigrant visa waiver pilot program (VWPP) which waives the nonimmigrant visa requirement for the admission of certain aliens into the United States for a period not to exceed ninety days. This original provision authorized the participation of eight countries in the VWPP to be designated by the Secretary of State and the Attorney General, acting jointly from among countries meeting specific criteria. These original qualifying countries included: France; the Federal

Republic of Germany; Italy; Japan; the Netherlands; Sweden; Switzerland; and the United Kingdom. (See **Federal Register** publications 53 FR 24903–24904, June 30, 1988; 53 FR 50161–50162, December 13, 1988; and 54 FR 27120–27121, June 27, 1989.)

Pub. L. 101–649

On November 29, 1990, the President signed the Immigration Act of 1990 (Pub. L. 101–649, 104 Stat. 4978). Section 201 revised the VWPP set forth in section 313 of IRCA (Sec. 217 INA, 8 U.S.C. 1187). It removed the eight-country cap and extended the provisions of the VWPP to all countries that meet the qualifying criteria of the Visa Waiver Pilot Program and were designated by the Secretary of State and the Attorney General in consultation with the Secretary of State as Pilot Program countries thereunder.

Effective October 1, 1991, Andorra, Austria, Belgium, Denmark, Finland, Iceland, Liechtenstein, Luxembourg, Monaco, New Zealand, Norway, San Marino, and Spain, having met all of the requirements for participants in the nonimmigrant Visa Waiver Pilot Program, were added as participants in the Program. (See 56 FR 46716–46717, September 13, 1991.) Brunei was designated as a participant in the Visa Waiver Pilot Program in an interim rule published at 58 FR 40581–40586 of the **Federal Register** of July 26, 1993.

Pub. L. 103–415

Section 1(m) of Pub. L. 103–415 again amended section 217 of the INA to extend the Visa Waiver Pilot Program through September 30, 1995.

Pub. L. 103–416

Section 210 of the Immigration and Nationality Technical Corrections Act of 1994 (INTC) (Pub. L. 103–416) amended section 217 of the INA extending the Visa Waiver Pilot Program to September 30, 1996. Section 211 of INTC created and established criteria for a new probationary qualification status for countries which met the criteria for that status under the VWPP and which were designated by the Secretary of State and the Attorney General, acting jointly, as countries whose nationals benefitted from the waiver of the nonimmigrant B–1/B–2 visa requirement.

The Department published an interim rule [59 FR 15872] to implement the provisions of sections 210 and 211 (Pub. L. 103–416) on March 28, 1995. Ireland was determined to be the only country which met the criteria set forth for such probationary qualification status. On July 8, 1996 Argentina was added as a non-probationary VWPP country (61 FR 35628–35629) and Australia became a non-probationary participating country on July 29, 1996 (61 FR 39318).

Pub. L. 104–208

On September 30, 1996 the President signed Pub. L. 104–208, the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, (IIRIRA). Section 635 of this law again amended INA 217 by extending the Program until September 30, 1997. This law also named the Attorney General as the principal designator of VWPP countries, eliminated probationary VWPP qualification status and made countries then in such status (Ireland being the only country) permanent participating VWPP countries subject to the same disqualification criteria established for other VWPP countries.

Requirements for VWPP Participation

For a country to qualify as a participant in the VWPP, the country must agree to waive the visa requirement for nationals of the United States entering for business or pleasure for ninety (90) days or less, must meet statutorily prescribed limits on visa refusal rates for the prior two year period as well as the prior year; must meet statutorily prescribed limits on rates of exclusion at ports of entry and on overstay rates, and must have a machine readable passport program. The Attorney General, in consultation with the Secretary of State, has determined that Slovenia has met these requirements, and Slovenia, therefore, is added effective September 30, 1997 as a participating country in the Visa Waiver Pilot Program. (See the Immigration and Naturalization Service rule also published in this issue of the **Federal Register**.)

Interim Rule

The implementation of this rule as an interim rule, with a 30-day provision for post-promulgation public comments, is based upon the ''good cause'' exceptions set forth at 5 U.S.C. 553(b)(B) and 553(d)(3). Because this rule will facilitate tourist and business travel to and from Slovenia, delay for pre-promulgation public comment would be contrary to the public interest. This rule will, therefore, become effective upon publication in the **Federal Register.**

In accordance with 5 U.S.C. 605(b) (Regulatory Flexibility Act), it is certified that this rule does not have a ''significant adverse economic impact'' on a substantial number of small entities, because it is inapplicable. This rule is exempt from E.O. 12866 (Regulatory Planning and Review) but has been coordinated with the Immigration and Naturalization Service because action by the Attorney General is required under section 217 of the INA, as amended. The rule imposes no reporting or record-keeping action from the public requiring the approval of the Office of Management and Budget under the Paperwork Reduction Act. This rule has been reviewed as required by E.O. 12988 (Civil Justice Reform) and is certified to be in compliance therewith.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Visas, Passports, Temporary Visitors, Waivers.

This interim rule, with request for comments, amends Part 41, Title 22 by eliminating the pilot program which allowed countries to participate in the Program with probationary status and by adding Ireland and Slovenia to the list of participating countries in the Visa Waiver Pilot Program.

PART 41—[AMENDED]

1. The authority citation for Part 41 continues to read:

Authority: 8 U.S.C. 1104.

2. Accordingly, paragraph (l) of § 41.2 is revised to read as follows:

§ 41.2 Waiver by the Secretary of State and Attorney General of passport and/or visa requirements for certain categories of nonimmigrants.

* * * * *

(l) *Visa waiver pilot program*. (1) Notwithstanding the provisions of paragraphs (a) through (k) of this section, a visa is not required of any person who seeks admission to the United States for a period of 90 days or less as a visitor for business or pleasure and who is eligible to apply for admission to the United States as a Visa Waiver Pilot Program applicant.

(2) Countries designated as pilot program countries under paragraph (l)(1), of this section are: the United Kingdom (effective July 1, 1988); Japan (effective December 15, 1988); France and Switzerland (effective July 1, 1989); The Federal Republic of Germany and Sweden (effective July 15, 1989); Italy and The Netherlands (effective July 29, 1989); Andorra, Austria, Belgium, Denmark, Finland, Iceland, Liechtenstein, Luxembourg, Monaco, New Zealand, Norway, San Marino, and Spain (effective October 1, 1991); Brunei (effective July 29, 1993); Ireland (effective April 1, 1995); Argentina (effective July 8, 1996); Australia (effective July 29, 1996) and Slovenia (effective September 30, 1997).

* * * * *

Dated: September 25, 1997.

Mary A. Ryan,

Assistant Secretary for Consular Affairs.

[FR Doc. 97–25951 Filed 9–29–97; 8:45 am]

BILLING CODE 4710–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300554; FRL–5744–8]

RIN 2070-AB78

Carfentrazone-ethyl; Temporary Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary tolerance for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate) and its major wheat metabolites in or on corn (fodder, forage, and grain) and wheat (grain, hay, and straw). FMC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170).

DATES: This regulation is effective September 30, 1997. Objections and requests for hearings must be received by EPA on or before December 1, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300554, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP–300554], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300554. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 1997 (62 FR 27040) (FRL–5717–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing a temporary tolerance for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate), and its metabolite in or on field corn forage, fodder, and grain at 0.15 ppm; and for wheat hay, straw, and grain at 0.20 ppm part per million (ppm). This tolerance will expire on May 8, 1998. This tolerance request was submitted along with an application for an experimental use permit (EUP). The EUP proposed the experimental use of carfentrazone-ethyl on corn and wheat. Under FIFRA, section 5 for experimental use permits, a temporary tolerance level must be established if a pesticide may reasonably be expected to result in any residue in or on food or feed use.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects*. For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than