hour fax-on-demand service, tel.: 202/622–0077.

Background

On July 4, 1999, the President issued Executive Order 13129 (64 FR 36759, July 7, 1999), invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) ("IEEPA") and the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (the "NEA"). In Executive Order 13129, the President determined that the actions and policies of the Taliban in Afghanistan, in allowing territory under its control in Afghanistan to be used as a safe haven and base of operations for Usama bin Ladin and Al-Qaida, constituted an unusual and extraordinary threat to the national security and foreign policy of the United States and declared a national emergency to deal with that threat. In response to this national emergency, the President, in Executive Order 13129, ordered the blocking of all property and interests in property of the Taliban and of persons determined to be owned or controlled by, or to act for or on behalf of, the Taliban, or to provide financial, material, or technological support for, or services in support of, any of the foregoing. In addition, Executive Order 13129 imposed a trade embargo against the Taliban, any persons designated pursuant to the order, and the territory of Afghanistan controlled by the Taliban. On January 11, 2001, the Department of the Treasury's Office of Foreign Assets Control ("OFAC") issued the Taliban (Afghanistan) Sanctions Regulations, 31 CFR part 545, to implement Executive Order 13219 (66 FR 2726, January 11, 2001).

On September 23, 2001, the President issued Executive Order 13224 (66 FR 49079, September 25, 2001), invoking the authority of, *inter alia,* IEEPA, the NEA, and section 5 of the United Nations Participation Act of 1945, as amended (22 U.S.C. 287c). In Executive Order 13224, the President determined that grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the terrorist attacks in New York, Pennsylvania, and the Pentagon committed on September 11, 2001, and the continuing and immediate threat of further attacks on United States nationals or the United States constitute an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States and declared a national emergency to deal with that threat. Executive Order 13224 blocks the property and interests in property of foreign persons listed in the Annex to the order or determined to have committed or to pose a significant risk of committing acts of terrorism that threaten U.S. nationals or the United States, as well as of, *inter alia,* persons determined to be owned or controlled by, to act for or on behalf of, or to provide financial, material, or technological support for, or financial or other services to or in support of, such acts of terrorism or those persons listed in the Annex or determined to be subject to the order. On June 6, 2003, OFAC issued the Global Terrorism Sanctions Regulations, 31 CFR part 594 (68 FR 34196, June 6, 2003) (the "GTSR"), to carry out the purposes of Executive Order 13224.

On July 2, 2002, the President issued Executive Order 13268 (67 FR 44751, July 3, 2002), determining that the situation that gave rise to the declaration of a national emergency in Executive Order 13129 of July 4, 1999, with respect to the Taliban was significantly altered. As a result, the President terminated the national emergency declared in Executive Order 13129 with respect to the actions and policies of the Taliban in Afghanistan and revoked that order. In addition, Executive Order 13268 amended the Annex to Executive Order 13224 of September 23, 2001, by adding the Taliban and one individual who had previously been listed in the Annex to Executive Order 13129, Mohammed Omar, the leader of the Taliban. As a result, transactions involving the Taliban remain subject to the GTSR.

Accordingly, OFAC is removing the Taliban (Afghanistan) Sanctions Regulations, 31 CFR part 545, from 31 CFR chapter V. Pursuant to section 202 of the NEA and section 4 of Executive Order 13268, removal of this part does not affect ongoing enforcement proceedings or prevent the initiation of enforcement proceedings based on an act committed prior to the date of Executive Order 13268 where the relevant statute of limitations has not run.

Public Participation

Because the Taliban (Afghanistan) Sanctions Regulations involve a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, as amended, and the Administrative Procedure Act (5 U.S.C. 553), requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

List of Subjects in 31 CFR Part 545

Administrative practice and procedure, Afghanistan, Banks, Banking, Blocking of assets, Foreign investments in the United States, Foreign trade, Penalties, Reporting and recordkeeping requirements, Taliban, Travel restrictions.

For the reasons set forth in the preamble, and under the authority of 50 U.S.C. 1701–1706 and Executive Order 13268, 31 CFR chapter V is amended by removing part 545.

Dated: May 25, 2011.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2011–13581 Filed 5–31–11; 8:45 am]

BILLING CODE 4810–AL–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0361; FRL–8870–7]

Ethylene Glycol; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of ethylene glycol (CAS Reg. No. 107–21–1) when used as a pesticide inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation. Huntsman, *et. al,* submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethylene glycol. Also, this regulation establishes an exemption from the requirement of a tolerance for residues of ethylene glycol (CAS Reg. No. 107–21–1) when used as an inert ingredient as an encapsulating agent for pesticides being applied post-harvest as residual, and crack and crevice sprays in and around food and nonfood areas of residential and nonresidential structures, including food handling establishments, with no limit. The Sumitomo Chemical Company submitted a petition to EPA under FFDCA, requesting an establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethylene glycol.

DATES: This regulation is effective June 1, 2011. Objections and requests for hearings must be received on or before August 1, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for these actions under docket identification (ID) number EPA–HQ–OPP–2011–0361. 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., 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7894; e-mail address: *austin.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0361 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 1, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0361, 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.

II. Petition for Exemption

EPA received two petitions requesting that 40 CFR 180.910 and 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ethylene glycol.

In the **Federal Register** of July 9, 2008 (73 FR 39291) (FRL–8371–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7355) by Huntsman, 10003 Woodloch Forest Drive, The Woodlands, TX 77380; Dow AgroSciences L.L.C., 9330 Zionsville Road, Indianapolis, Indiana 46268; Nufarm Americas Inc., 150 Harvester Drive Suite 220, Burr Ridge, Illinois 60527; BASF, 26 Davis Drive, Research Triangle Park, NC 27709; Stepan Company, 22 W. Frontage Road, Northfield, IL 60093; Loveland Products Inc., PO Box 1286, Greeley, CO 80632; and Rhodia Inc., CN 1500, Cranbury, New Jersey 08512. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ethylene glycol (CAS Reg. No. 107–21–1) when used as an inert ingredient solvent, stabilizer and/or antifreeze without limitation in pesticide formulations applied to pre-harvest crops. That notice referenced a summary of the petition prepared by Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc., which is available in the docket, *http://www.regulations.gov.* The Agency received one comment in response to the notice of filing.

Also, in the **Federal Register** of August 4, 2004 (69 FR 47149) (FRL–7367–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 4E6828) by the Sumitomo Chemical Company, Ltd., 5–33 Kitahama, 4-chrome, chuo-ku, Osaka 541–8550 Japan. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of ethylene glycol (CAS Reg. No. 107–21–1) when used as an inert ingredient in encapsulating agents for pesticides being applied post-harvest as residual, and crack and crevice sprays in and around food and nonfood areas of residential and nonresidential structures, including food handling establishments, with no limit. That notice referenced a summary of the petition prepared by the Sumitomo Chemical Company, which is available

in the docket, *http://www.regulations.gov.* The Agency received one comment in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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) of FFDCA 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) of FFDCA 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ethylene glycol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ethylene glycol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by ethylene glycol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Acute oral toxicity in rodents, as expressed as a lethal dose $(LD)_{50}$, ranges from 1,500 milligram/kilogram (mg/kg) to 8,800 mg/kg. In the guinea pig, the acute oral toxicity is about 6,600 mg/kg and in the rabbit, 5,000 mg/kg. In the dog, the acute oral LD_{50} is greater than 8,000 mg/kg. It is minimally irritating to the eyes and skin of rabbits. Acute inhalation and dermal toxicity data were not identified. However, given the vapor pressure of undiluted ethylene glycol (0.092 millimeter (mm) mercury (Hg) @ 25 °C) acute inhalation concerns are not expected. According to the National Institute of Occupational Safety and Health (NIOSH) (1999), a "harmful contamination of the air will be reached rather slowly on evaporation of this substance at 20 °C."

In subchronic and chronic testing, rats were more sensitive to the effects of ethylene glycol treatment than mice at comparable dose levels. Among rats, males appeared to be more sensitive than females. In subchronic toxicity testing in rats and mice, the kidney was adversely affected in all studies considered. Effects common to all studies include increased kidney weights, formation of lesions, and formation of oxalate crystals. In the rat, NOAELs range from 71 to 4,000 mg/kg/day and in the mouse the NOAELs range from 1,000 to 3,230 mg/kg/day. In chronic testing in rats, kidney effects similar to those seen in subchronic testing were observed. In addition, effects to the liver were seen (*i.e.,* decreased liver weight; fatty changes). The lowest NOAEL (71 mg/kg/day) in the toxicity database occurred in a subchronic toxicity study in rats. The LOAEL in this study was 180 mg/kg/day based on kidney effects. In chronic studies, the lowest NOAEL of 150 mg/kg/day was observed in rats, the most sensitive species.

Developmental toxicity testing was conducted in rats, mice, and rabbits. Overall, fetal toxicity was exhibited as increased fetal deaths, skeletal and external malformations, and reduced body weight. Maternal toxicity was manifested as decreased body weight gain, kidney effects (lesions, increased organ weight), and liver effects (decreased organ weight). The relative sensitivities of these species in terms of developmental toxicity during organogenesis are: Mice are the most sensitive and rabbits are the least sensitive. For maternal toxicity per se the sensitivity is: Rats are the most sensitive and rabbits are the least sensitive.

In rabbits, statistically-significant fetal developmental toxicity was not observed; however, maternal toxicity was seen at 2,000 mg/kg/day; it was manifested as renal toxicity (lesions, oxalate formation). In rats, fetal toxicity was seen at doses ranging from 1,000 mg/kg/day to 2,500 mg/kg/day. It manifested as decreased viability (2,250 mg/kg/day); decreased body weight gain and decreased pup weight (1,000 to 2,500 mg/kg/day); and skeletal effects and malformations (1,000 to 2,500 mg/kg/day). The skeletal effects and malformations included: Poorly ossified and unossified vertebral centra; decrease in total ossification; hydrocephaly; and pup malformation. Maternal toxicity in rats was manifested as: Decreased body weight gain (1,250 to 2,500 mg/kg/day); decreased liver weight (5,000 mg/kg/day); and kidney effects such as lesions and increased weight (1,250 to 2,500 mg/kg/day). In mice, fetal toxicity was seen at doses ranging from 500 to 1,500 mg/kg/day. As with rats it manifested as decreased

fetal body weight and/or weight gain (750 to 1,500 mg/kg/day) and skeletal effects (500 to 1,500 mg/kg/day) which included: Pup malformations, fused ribs and arches, poor ossification in thoracic and lumbar centra, and increased occurrence of an extra 14th rib. The lowest developmental NOAEL in mice was 150 mg/kg/day. Maternal toxicity was demonstrated as decreased weight gain (1,500 mg/kg/day) and decreased liver weight (1,500 mg/kg/day).

The reproductive toxicity of ethylene glycol was studied in rats and mice. In rats, no reproductive toxicity was noted. In mice, reproductive toxicity was seen at doses ranging from 897 to 2,826 mg/kg/day. It manifested as: Decreased numbers of live implants and increased number of dead implants; sperm effects (abnormal sperm, decreased motility, decreased sperm count); testicular lesions; and decreased testes weight.

Ethylene glycol is not known to be mutagenic. In a standard battery of *in vitro* genotoxicity assays conducted by the National Toxicology Program; Health and Human Services (NTP; HHS 1993), all results were negative. Ethylene glycol is not considered to be carcinogenic. In carcinogenicity testing conducted by the NTP in rats and mice, no evidence of carcinogenic potential was noted. Therefore, based on the lack of mutagenicity and lack of carcinogenicity in rodents, ethylene glycol is not expected to pose a carcinogenic risk in humans.

Metabolism studies demonstrated that ethylene glycol was rapidly absorbed, metabolized and excreted. It is primarily metabolized via the liver and kidneys. Ethylene glycol and metabolites (glycolic acid and oxalic acid) are primarily excreted in the urine within 12–18 hours after administration.

Specific information on the studies received and the nature of the adverse effects caused by the ethylene glycol, as well as, the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document "800009, Ethylene Glycol; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pp. 7–24 in EPA–HQ–OPP–2008–0474 and EPA–HQ–OPP–2004–0207.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD)(acute = a and chronic = c) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for ethylene glycol used for human risk assessment is shown in the Table of this unit.

No acute endpoint of concern for general population was identified in the available data base. However, the endpoint of concern for females 13 plus age was identified in a developmental toxicity study in mice with a NOAEL of 150 mg/kg/day and LOAEL of 500 mg/kg/day based on an increased incidence of total malformations and bilateral extra rib14.

The endpoint selected for the cRfD was based on a chronic toxicity study in rats. The NOAEL in this study was 150 mg/kg/day based on kidney lesions and mortality observed at 300 mg/kg/day. Although 71 mg/kg/day is the lowest NOAEL in the database identified in a subchronic study in rats, the confidence in this subchronic study is low because subchronic and chronic studies support the NOAEL of 150 mg/kg/day and above. The NOAEL 150 mg/kg/day selected for the cRfD is protective of any developmental effects. Therefore, the Agency selected the point of departure of 150 mg/kg/day to establish the cRfD.

The EPA Integrated Risk Information System (IRIS) established a oral cRfD based on the NOAEL of 200 mg/kg/day and uncertainty factor 100. The currently chosen endpoint and the dose used for this risk assessment provide the most conservative assessment.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHYLENE GLYCOL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	NOAEL = 150 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.5 mg/kg/day ..... aPAD = 1.5 mg/kg/day	Developmental toxicity study—mice. LOAEL = 500 mg/kg bw/day, based on increased incidence of total malformations and bilateral extra rib 14.
Chronic dietary (All populations).	NOAEL = 150 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 1.5 mg/kg/day .... cPAD = 1.5 mg/kg/day	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.
Incidental oral short-term (1 to 30 days).	NOAEL = 150 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.
Incidental oral intermediate-term (1 to 6 months).	NOAEL = 150 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHYLENE GLYCOL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term (1 to 30 days).	NOAEL = 150 mg/kg/day (dermal absorption rate = 25%. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.
Dermal intermediate-term (1 to 6 months).	NOAEL = 150 mg/kg/day (dermal absorption rate = 25% when appropriate). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.
Inhalation short-term (1 to 30 days).	NOAEL = 150 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.
Inhalation (1 to 6 months).	NOAEL = 150 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity study. LOAEL = 300 mg/kg/day based on kidney lesions and death in males.
Cancer (Oral, dermal, inhalation).	Not expected to be carcinogenic based on the lack of mutagenicity and lack of carcinogenicity in rodents.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ethylene glycol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from ethylene glycol in food as follows:

i. *Acute and chronic exposure.* In conducting the acute and chronic dietary exposure assessments, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for the ethylene glycol. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that

could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

ii. *Cancer.* Ethylene glycol is not expected to be carcinogenic since it was negative for carcinogenicity in mice and rats in the available published studies and there was a negative response for mutagenicity. Since the Agency has not identified any concerns for carcinogenicity relating to ethylene glycol, a dietary exposure assessment to evaluate cancer risk was not performed.

iii. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for ethylene glycol. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ethylene glycol, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Ethylene glycol may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure. A screening level residential exposure and risk assessment was completed for products containing ethylene glycol as inert ingredients. The ethylene glycol inerts may be present in consumer personal (care) products and cosmetics (at concentrations up to 1%) (http://hpd.nlm.nih.gov/index.htm). The Agency conducted exposure assessments based on end-use product application methods and labeled application rates. The Agency conducted an assessment to represent worst-case residential exposure by assessing ethylene glycol in pesticide formulations used in crack and crevice applications. The Agency conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from ethylene glycol in pesticide formulations.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found ethylene glycol to share a common mechanism of toxicity with any other substances, and ethylene glycol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethylene glycol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the case of the ethylene glycol, some of the available studies suggest increased susceptibility to the offspring of rodents following pre-natal and post-natal exposure. However, the effects (described in this unit) occurred at doses that were > 500 mg/kg/day. The established cRfD of 1.5 mg/kg/day will be protective of these effects. Therefore, the concern for increased fetal susceptibility is low and there are no residual concerns.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for ethylene glycol is adequate. The following acceptable studies are available:

Developmental toxicity studies in rodents (6);

Multi-generation reproduction studies in rodents (4);

Subchronic toxicity studies in multiple species;

Inhalation and dermal toxicity studies;

Chronic/carcinogenicity studies in rodents (5).

ii. Signs of neurotoxicity (when observed) occurred at high doses and at doses above that which produced kidney toxicity. The established cRfD of 1.5 mg/kg/day (NOAEL = 150 mg/kg/day) is protective of kidney toxicity and is therefore protective of neurotoxic effects. Also, the International Programme on Chemical Safety Concise International Chemical Assessment Document 45 Ethylene Glycol: Human Health Aspects (IPCS CICAD 2002) concluded that "data are limited, results of identified toxicity studies conducted (via oral, inhalation, or dermal routes) in rodents, rabbits, and monkeys do not indicate that neurological effects are critical end-points for ethylene glycol." IPCS (2002) also states that generally neurotoxicity effects occur at a dose higher than the dose producing kidney toxicity. Since the current cRfD is protective of kidney toxicity, the concern for neurotoxicity is low to none. Therefore, EPA concluded that the developmental neurotoxicity is not required.

iii. Evidence of potential immunotoxicity was observed in a subchronic toxicity study in rats. Decreased relative thymus weights were observed at 4,000 mg/kg/day. Again, this effect occurred at a high dose and at a dose above that which produced kidney toxicity. The established cRfD of 1.5 mg/kg/day (NOAEL = 150 mg/kg/day) is protective of kidney toxicity and is approximately 2,600 times lower than the dose where decreased relative thymus weights were observed. Therefore, the cRfD will be protective of this immunotoxicity effects. The IPCS CICAD for ethylene glycol finds that although "data are limited, results of

identified toxicity studies conducted (via oral, inhalation, or dermal routes) in rodents, rabbits, and monkeys do not indicate that immunological effects are critical end-points for ethylene glycol." (IPCS 2002).

iv. Evidence of increased susceptibility was not observed in the developmental toxicity study in the rabbit. However, evidence of increased susceptibility was observed following prenatal exposure to ethylene glycol in mice. An increased incidence of total malformations and bilateral extra rib 14 were observed at 500 mg/kg/day. These effects occurred in the absence of maternal toxicity. In a developmental study in rats, there was evidence of qualitative fetal susceptibility. Maternal (tubular dilation and regeneration in the kidneys, increased gestational period, and decreased relative kidney weights) and developmental (decreased pup weight, increased cumulative mortality/litter, increased incidence of hydrocephaly, decreased relative kidney weights, decreased absolute brain weights, and increased incidences of hydrocephaly; defects in ribs, sternebrae, and vertebrae) were observed at the same dose (1,250 mg/kg/day). There was no evidence of increased fetal susceptibility in another developmental study in rats, maternal (pre-implantation loss) and developmental (poorly ossified and unossified vertebral centra) effects were observed at the same dose (1,000 mg/kg/day). However, there was a well established NOAEL in these two developmental toxicity studies in rats protecting fetuses. In addition, these fetal effects were generally seen at relatively high doses. In a reproduction study in mice, increased fetal susceptibility was observed but again it occurred above the limit dose. Developmental toxicity manifested as decrease number of live pups/litter, and mean live pup weight was observed in the absence of maternal toxicity at 1,640 mg/kg/day.

In another reproduction study in mice, maternal (kidney lesions and oxalate crystals) and developmental toxicity (decrease in pup weight adjusted for litter size) were observed at 897 mg/kg/day.

However, the concern for this increased susceptibility was low based on the following rationale:

a. There is a well established NOAEL in these studies protecting fetuses/offspring from the aforementioned effects;

b. Although increased susceptibility was observed, this occurred at doses close to the limit dose of 1,000 mg/kg/day;

c. The effects seen in the developmental study were not reproduced in the reproduction studies; and

d. The established chronic reference dose of 1.5 mg/kg/day will be protective of these effects. Therefore, based on the weight of evidence the concern for increased fetal susceptibility is low.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using very conservative assumptions. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to ethylene glycol in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by ethylene glycol.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to ethylene glycol from food and water will utilize 26.5% of the aPAD for females 13–49, the only population group identified as potentially facing an acute risk from exposure to ethylene glycol.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ethylene glycol from food and water will utilize 12.8% of the cPAD for the general population and 41.6% of the cPAD for children 1–2 yrs old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Ethylene glycol is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to ethylene glycol.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 200 for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from homeowner mixer/loader/applicators using a trigger sprayer with a high end post application dermal exposure from contact with treated lawns. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 170 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's LOC for ethylene glycol is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Ethylene glycol is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to ethylene glycol.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 580 for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from homeowner mixer/loader/applicators using a trigger sprayer with a high end post application dermal exposure from contact with treated lawns. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 200 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's LOC for ethylene glycol is a MOE of 100

or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to ethylene glycol.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to ethylene glycol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for ethylene glycol.

C. Response to Comments

The two comments were received from private citizens who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commentors' concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for ethylene glycol (107–21–1) when used as an inert ingredient (in encapsulating agents for pesticides being applied post-harvest as residual, and crack and crevice sprays in and around food and nonfood areas of residential and nonresidential structures, including food handling establishments) and 40 CFR 180.920 for ethylene glycol when used as an (inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation) applied to pre-harvest crops.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. 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 to each House of the Congress and to 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 18, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Ethylene glycol (CAS Reg. No. 107–21–1)	Without limitation	Encapsulating agent for pesticides being applied post-harvest as residual, and crack and crevice sprays in and around food and nonfood areas of residential and nonresidential structures, including food handling establishments.
* * * * * * *		

■ 3. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Ethylene glycol (CAS Reg. No. 107–21–1)	Without limitation	Pesticide inert ingredient as a solvent, stabilizer and/or anti-freeze.
* * * * * * *		

[FR Doc. 2011–13577 Filed 5–31–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0426; FRL–8873–5]

Pyraflufen-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraflufen-ethyl in or on multiple commodities which are identified and discussed later in this document. Nichino America, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 1, 2011. Objections and requests for hearings must be received on or before August 1, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0426. 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., 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: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1243; e-mail address: *montague.kathryn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an