contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: July 18, 2005.

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. Section 180.556 is amended by alphabetically adding the commodity to the table in paragraph (a) to read as follows:

§ 180.556 Pymetrozine; tolerances for residues.

(a) * * *

Commodity	Parts per million
Asparagus	0.04
* * *	* *

* * * * *

[FR Doc. 05–14598 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0038; FRL–7726–8]

2,4-D; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of 2,4-dichlorophenoxyacetic acid (2,4-D) in or on hop, soybean, and wild rice . Interregional Research Project Number 4 (IR-4) and the Industry Task Force II on 2,4-D Research Data (Task Force) and its registrant members and affiliates on behalf of IR-4 requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 27, 2005. Objections and requests for

hearings must be received on or before September 26, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2005–0038. 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., 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 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: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental ProtectionAgency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of March 14, 2002 (67 FR 11480) (FRL–6826–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E4636) by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.142 be amended by establishing a tolerance for residues of the herbicide 2,4-D in or on wild rice at 0.1 parts per million (ppm). That notice included a summary of the petition prepared by Rhone-Poulenc Ag Co., the registrant. In the **Federal Register** of December 15, 2004 (69 FR 75066) (FRL–7688–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E3060) by the Task Force and its registrant members and affiliates, 1900 K St., NW., Washington, DC 20006 on behalf of IR-4. The petition requested that 40 CFR 180.142(a)(11) be amended by removing the expiration date of December 31, 2004 for 2,4-D in or on the raw agricultural commodity soybean seed at 0.02 ppm. That notice included a summary of the petition prepared by the Task Force, the petitioner. In the **Federal Register** of April 13, 2005 (70 FR 19442) (FRL–7707–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E6352) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide 2,4-D in or on hop at 0.05 ppm. That notice included a summary of the petition prepared by IR-4, the petitioner. Two comments were received in response to the notices of filing and they are addressed in Unit IV.D.

Section 408(b)(2)(A)(i) of 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) 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of 2,4-D on hop at 0.05 ppm, soybean at 0.02 ppm, and wild rice at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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 toxic effects caused by 2,4-D are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—2,4-D SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study type	Results
870.3100	90–Day oral toxicity—rodents—rats	NOAEL = 15 milligrams/kilogram/day (mg/kg/day) LOAEL = 100 mg/kg/day based on decreases in body weight/gain, alterations in hematology and clinical chemistry (decreased T3 and T4) parameters, and cataract formation in females.
870.3150	90–Day oral toxicity—nonrodents—beagle dogs	NOAEL = 1 mg/kg/day LOAEL = 3 mg/kg/day based on decreased body weight/body-weight gain and food consumption (males), alterations in clinical chemistry parameters (increased blood urea nitrogen (BUN) (both sexes), creatinine (males)), and decreased testis weight in males.
870.3150	90–Day oral toxicity—nonrodents—beagle dogs	NOAEL = 1 mg/kg/day LOAEL = 3.75 mg/kg/day based on decreased body-weight gain (both sexes) and food consumption (males), as well as alterations in clinical chemistry parameters (increased BUN, creatinine, and alanine aminotransferase) in both sexes, and decreased testes weight and slightly higher incidence of hypospermatogenesis/juvenile testis and inactive/juvenile prostate were observed.
870.3200	21–Day dermal toxicity	NOAEL = 1,000 mg/kg/day LOAEL = >1,000 mg/kg/day based on no adverse effects at the limit dose.
870.3700	Prenatal developmental—rodents—rats	*Maternal*: NOAEL = 25 mg/kg/day LOAEL = 75 mg/kg/day based on decreased body-weight gains. Survival was not affected by treatment. *Developmental*: NOAEL = 25 mg/kg/day LOAEL = 75 mg/kg/day based on skeletal abnormalities.
870.3700	Prenatal developmental—nonrodents—rabbits	*Maternal*: NOAEL = 30 mg/kg/day LOAEL = 90 mg/kg/day based on clinical signs (ataxia, decreased motor activity, loss of righting reflex, cold extremities), abortion (2), decreased body-weight gains. Survival was not affected by treatment. *Developmental*: NOAEL = 30 mg/kg/day LOAEL = 90 mg/kg/day based on abortions.
870.3800	Reproduction and fertility effects—rats	*Parental/Systemic*: NOAEL = 5 mg/kg/day LOAEL = 20 mg/kg/day based on decreased female body weight/body-weight gain (F1) and renal tubule alteration in males (F0 and F1). *Reproductive*: NOAEL = 20 mg/kg/day LOAEL = 80 mg/kg/day based on an increase in gestation length (F0 females producing F1b pups). *Offspring*: NOAEL = 5 mg/kg/day LOAEL = 20 mg/kg/day based on decreased pup body weight (F1b). At 80 mg/kg/day, there was an increase in dead pups.
870.4100	Chronic toxicity—dogs	NOAEL = 1 mg/kg/day LOAEL = 5 mg/kg/day based on decreased body-weight gain (both sexes) and food consumption (females), as well as alterations in clinical chemistry parameters (increased BUN, creatinine, and alanine aminotransferase, decreased glucose) in both sexes, and decreased brain weight in females, and histopathological lesions in liver and kidneys.

TABLE 1.—2,4-D SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study type	Results
870.4300	Combined chronic toxicity carcinogenicity —rodents (rats)	NOAEL = 5 mg/kg/day LOAEL = 75 mg/kg/day based on decreased body-weight gain (females) and food consumption (females), alterations in hematology (decreased red blood cells (RBC), hematocrit (HCT), and hemoglobin (HGB) (females), platelets (both sexes)) and clinical chemistry parameters (increased creatinine (both sexes), alanine and aspartate aminotransferases (males), alkaline phosphatase (both sexes), decreased T4 (both sexes), glucose (females), cholesterol (both sexes), and triglycerides (females)), increased thyroid weights (both sexes at study termination), and decreased testes and ovarian weights. At highest dose tested (HDT), there were microscopic lesions in the eyes, liver, adipose tissue, and lungs. There was no evidence of carcinogenicity
870.4300	Carcinogenicity—mice	NOAEL = 5 mg/kg/day LOAEL = 62/150 mg/kg/day based on an increased absolute and/or relative kidney weights and an increased incidence of renal microscopic lesions. There was no evidence of carcinogenicity
870.5265	Gene mutation Ames, reverse mutation	No evidence of bacterial mutation in *S. typhimurium* strains TA1535, TA1537, TA1538, TA98, TA100, with and without S9.
870.5395	*In vivo* erythrocyte micro-nucleus assay Institute for Cancer Research (ICR) mice	No significant increase in bone marrow polychromatic erythrocytes.
870.5375	Cytogenetics *in vitro* chromosome aberration (human lymphocytes)	No evidence of increased chromosome aberrations in human lymphocytes.
870.5385	Cytogenetics *in vivo* chromosome aberration (Wistar rat bone marrow)	Equivocal (+ at top 2 doses, but results were similar to dimethyl sulfoxide (DMSO) control).
870.5450	Other effects (Unscheduled DNA synthesis assay)	No evidence of induction of unscheduled DNA synthesis.
870.6200	Acute neurotoxicity screening battery—rats	NOAEL = 67 mg/kg/day LOAEL = 227 mg/kg/day based on an increased incidence of incoordination and slight gait abnormalities (described as forepaw flexing or knuckling) and decreased total motor activity.
870.6200	Subchronic neurotoxicity screening battery—rats	NOAEL = 75 mg/kg/day LOAEL = 150 mg/kg/day based on increased forelimb grip strength.
870.7485	Metabolism and pharmacokinetics—rats	85.5%–93.7% of dose eliminated in urine; 3.6%–10.5% of dose eliminated via the feces; no differences noted between the sexes; at the high-dose level, it appears that a nonlinear region (decreased clearance) is being reached in the disposition of 2,4-D. Parent 2,4-D was the major metabolite found in urine (72.9%–90.5% of the oral dose), with small amounts of uncharacterized compounds (0.6%–1.3% and 0%–0.7%) being found in the urine.
870.7600	Dermal penetration	5.8%
	Special studies pharmacokinetics/ metabolism study (single exposure) Fischer 344 ratand beagle dogs	Study designed specifically to compare the rat and dog with respect to the excretion of 2,4-D and the relevancy of the dog data for risk assessment.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or UFs may be used:''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants

and children primarily as a result of FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for 2,4-D used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR 2,4-D FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, interspecies and intraspecies and any traditional UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age)	NOAEL = 25 mg/kg/day UF = 1,000 Acute RfD = 0.025 mg/kg/day	Special FQPA SF = 1 aPAD = acute RfD/Special FQPA SF = 0.025 mg/kg/day	Rat developmental toxicity study LOAEL = 75 mg/kg/day based on skeletal abnormalities.
Acute dietary (General population including infants and children)	NOAEL = 67 mg/kg/day UF = 1,000 Acute RfD = 0.067 mg/kg/day	Special FQPA SF = 1 aPAD = acute RfD/Special FQPA SF = 0.067 mg/kg/day	Acute neurotoxicity study in rats LOAEL = 227 mg/kg/day based on gait abnormalities.
Chronic dietary (All populations)	NOAEL = 5 mg/kg/day UF = 1,000 Chronic RfD = 0.005 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/Special FQPA SF = 0.005 mg/kg/day	Rat chronic toxicity study LOAEL = 75 mg/kg/day based on decreased body-weight gain (females) and food consumption (females), alterations in hematology (decreased RBC, HCT, and HGB (females), platelets (both sexes)) and clinical chemistry parameters (increased creatinine (both sexes), alanine and aspartate aminotransferases (males), alkaline phosphatase (both sexes), decreased T4 (both sexes), glucose (females), cholesterol (both sexes), and triglycerides (females)).
Short-term incidental oral (1 to 30 days) (Residential)	Oral study NOAEL = 25 mg/kg/day	LOC for MOE = 1,000 (Residential)	Rat developmental toxicity study LOAEL = 75 mg/kg/day based on decreased maternal body-weight gain.
Intermediate-term incidental oral (1 to 6 months) (Residential)	Oral study NOAEL = 15 mg/kg/day	LOC for MOE = 1,000 (Residential)	Subchronic oral toxicity—rat LOAEL = 100 mg/kg/day based on decreased body weight/body-weight gain, alterations in some hematology (decreased platelets (both sexes)) and clinical chemistry (decreased T3 (females) and T4 (both sexes)) parameters, and cataract formation.
Short-term dermal (1 to 7 days) (Residential)	Oral study NOAEL = 25 mg/kg/day (Dermal absorption rate = 10 %)	LOC for MOE = 1,000 (Residential)	Rat developmental toxicity study LOAEL = 75 mg/kg/day based on decreased maternal body-weight gain and skeletal abnormalities.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR 2,4-D FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure scenario	Dose used in risk assessment, interspecies and intraspecies and any traditional UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Intermediate-term dermal (1 week to several months) (Residential)	Oral study NOAEL = 15 mg/kg/day (Dermal absorption rate = 10 %	LOC for MOE = 1,000 (Residential)	Subchronic oral toxicity—rat LOAEL = 100 mg/kg/day based on decreased body weight/body-weight gain, alterations in some hematology (decreased platelets (both sexes)) and clinical chemistry (decreased T3 (females) and T4 (both sexes)) parameters, and cataract formation.
Long-term dermal (Several months to lifetime) (Residential)	Oral study NOAEL = 5 mg/kg/day (Dermal absorption rate = 10 % when appropriate)	LOC for MOE = 1,000 (Residential)	Rat chronic toxicity study LOAEL = 75 mg/kg/day based on decreased body-weight gain (females) and food consumption (females), alterations in hematology (decreased RBC, HCT, and HGB (females), platelets (both sexes)) and clinical chemistry parameters (increased creatinine (both sexes), alanine and aspartate aminotransferases (males), alkaline phosphatase (both sexes), decreased T4 (both sexes), glucose (females), cholesterol (both sexes), and triglycerides (females)), increased thyroid weights (both sexes at study termination), and decreased testes and ovarian weights.
Short-term inhalation (1 to 7 days) (Residential)	Inhalation (or oral) study NOAEL = 25 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	Rat developmental toxicity study LOAEL = 75 mg/kg/day based on decreased maternal body-weight gain and skeletal abnormalities.
Intermediate-term inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL = 15 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	Subchronic oral toxicity—rat LOAEL = 100 mg/kg/day based on decreased body weight/body-weight gain, alterations in some hematology (decreased platelets (both sexes)) and clinical chemistry (decreased T3 (females) and T4 (both sexes)) parameters, and cataract formation.
Long-term inhalation (Several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL = 5 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	Rat chronic toxicity study LOAEL = 75 mg/kg/day based on decreased body-weight gain (females) and food consumption (females), alterations in hematology (decreased RBC, HCT, and HGB (females), platelets (both sexes)) and clinical chemistry parameters (increased creatinine (both sexes), alanine and aspartate aminotransferases (males), alkaline phosphatase (both sexes), decreased T4 (both sexes), glucose (females), cholesterol (both sexes), and triglycerides (females)), increased thyroid weights (both sexes at study termination), and decreased testes and ovarian weights.
Cancer (Oral, dermal, inhalation)	Not likely to pose a cancer risk based on the lack of carcinogenicity in a rat carcinogenicity study and a mouse carcinogenicity study.		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.142) for the residues of 2,4-D, in or on a variety of raw agricultural commodities, fish, meat, milk, poultry, and eggs. Risk assessments were conducted by EPA to assess dietary exposures from 2,4-D in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In conducting the acute dietary risk assessment EPA used Lifeline Model Version 2.0 (Lifeline) and the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID, Version 1.33). DEEM incorporates consumption data from United States Department of Agriculture's (USDA) Continuing

Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. Lifeline uses food consumption data from USDA's CSFII from 1994–1996 and 1998. Lifeline uses recipe files contained within the program to relate raw agricultural commodities (RACs) to foods ''as-eaten.'' Lifeline converts the RAC residues into food residues by randomly selecting a RAC residue value from the ''user defined'' residue distribution (created from the residue, percent crop treated (PCT), and processing factors data), and calculating a net residue for that food based on the ingredients' mass contribution to that food item. The following assumptions were made for the acute exposure assessments: For the acute analyses, tolerance-level residues were assumed for most food commodities with 2,4-D tolerances except the highest-field trial residue value was used for citrus commodities, and it was assumed that all of the crops included in the analysis were treated. One half of the average Level of Detection (LOD) from Pesticide Data Program (PDP) monitoring data was used as the milk exposure value because no milk sample contained detectable 2,4-D residues over several years of PDP. The PCT data were not used in the acute risk assessment.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used Lifeline and DEEM-FCID, Version 1.33. DEEM incorporates consumption data from USDA's CSFII, 1994–1996 and 1998. Lifeline uses food consumption data from the USDA's CSFII from 1994–1996 and 1998. Lifeline uses recipe files contained within the program to relate RACs to foods ''as-eaten.'' Lifeline converts the RAC residues into food residues by randomly selecting a RAC residue value from the ''user defined'' residue distribution (created from the residue, PCT, and processing factors data), and calculating a net residue for that food based on the ingredients' mass contribution to that food item. The following assumptions were made for the chronic exposure assessments: For the chronic analyses, tolerance-level residues were assumed for food commodities with 2,4-D tolerances except averages of field trial data and processing study factors were used for small grains, citrus, and sugarcane sugar and molasses; percentage of crop treated information was used for most commodities; and the highest observed groundwater monitoring concentration (15 parts per billion (ppb)) in drinking water is used to calculate the aggregate risk. One half of the average LOD from PDP monitoring data was used as the milk exposure value because no milk sample contained detectable 2,4-D residues over several years of PDP.

iii. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

TABLE 3.—PERCENT CROP TREATED (PCT) FOR REGISTERED 2,4-D USES

Crop	Acreage	PCT	Lbs./acre (ai)
Alfalfa	23,704,000	0.6	69,000
Almonds	583,000	10	70,000
Apples	477,000	36	250,000
Apricots	23,0008	8	3,000
Asparagus	77,000	15	20,000
Barley	5,914,000	43	1,290,000
Beans/peas, dry	2,133,000	3	30,000
Beans/peas, vegetable	677,000	1.2	8,000
Blueberries	62,000	0.5	200
Canola/rapeseed	1,281,000	2	11,000
Cherries	105,000	24	30,000
Corn, field	75,241,000	12	3,660,000

TABLE 3.—PERCENT CROP TREATED (PCT) FOR REGISTERED 2,4-D USES—Continued

Crop	Acreage	PCT	Lbs./acre (ai)
Cotton	13,793,000	3	234,000
Cranberries	32,000	9	6,000
Fallow, Summer	22,879,000	10	2,003,000
Flax	143,000	9	7,000
Filberts	31,000	58	35,000
Grapefruit	165,000	19	1,100
Grapes	1,006,000	2	13,000
Hay, other	33,777,000	8	1,824,000
Lemons	72,000	1.5	1,100
Millet	318,000	23	35,000
Nectarines	34,000	10	1,000
Oats	4,036,000	19	380,000
Oranges	940,000	7	20,000
Pasture/rangeland	469,536	5	16,371,000
Peaches	158,000	12	25,000
Peanuts	1,416,000	4	30,000
Pears	70,000	14	15,000
Pecans	496,000	5	20,000
Pistachios	100,000	5	5,000
Potatoes	1,291,000	2	4,000
Prunes/plums	151,000	17	25,000
Rice	3,231,000	17	527,000
Rye	298,000	21	30,000
Seed crops	1,383,000	36	275,000
Sorghum	9,077,000	16	667,000
Soybeans	70,993,000	7	2,410,000
Strawberries	47,000	7	5,000
Sugarcane	939,000	53	490,000
Sunflowers	2,040,000	4	50,000
Sweet Corn	678,000	5	15,000
Walnuts	229,000	9	40,000
Wheat, Spring	18,903,000	4	50,000
Wheat, Winter	42,403,000	24	5,140,000
Wild rice	26,000	10	600

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, State, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five. EPA uses a maximum PCT for acute dietary risk analysis. The

maximum PCT figure is the single-maximum value reported overall from available Federal, State, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five.

The Agency believes that the three conditions listed Unit III.C.1.iii. have been met. With respect to Condition 1 of Unit III.C.1.iii. , PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3 of Unit III.C.1.iii., regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which 2,4-D may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for 2,4-D in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of 2,4-D.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water Modeling System (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of 2,4-D for acute exposures are estimated to be 118 ppb for surface water. The EECs for chronic exposures are estimated to be 23 ppb for surface water. Based on actual monitoring of 2,4-D the acute and chronic exposures are 15 ppb for ground water.

3. *From non-dietary exposure*. The term''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

2,4-D is currently registered for use on the following residential non-dietary sites: Turf. The risk assessment was conducted using the following residential exposure assumptions: Homeowners (or others) may be exposed to 2,4-D while treating their lawns. All homeowner-use products are available in liquid or granular form. 2,4-D is applied using hose-end sprayers, pump sprayers, ready-to-use sprayers, broadcast spreaders, belly grinders, and hand application, either before or after seasonal weed emergence, at a rate up to 1.5 lbs./ai. 2,4-D uses in the residential setting include applications to home lawns. The following scenarios were assessed for residential post application risks: Toddlers playing on treated turf, adults performing yard work on treated turf, and adults playing golf on treated turf.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to 2,4-D and any other substances and 2,4-D does not appear to produce a toxic metabolite produced by other substances. EPA has also evaluated comments submitted that suggested there might be a common mechanism among 2,4-D and other named pesticides that cause brain effects. EPA concluded that the evidence did not support a finding of common mechanism for 2,4-D and the named pesticides. For the purposes of this tolerance action, therefore, EPA has not assumed that 2,4-D has 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 the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using UFs (safety) in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The toxicity database for 2,4-D includes acceptable developmental and reproductive toxicity studies. Developmental toxicity studies were conducted in both rats and rabbits for most 2,4-D forms. There is qualitative evidence of susceptibility in the rat developmental toxicity study with 2,4-D acid and DEA salt where fetal effects (skeletal abnormalities) were observed at a dose level that produced less severe

maternal toxicity (decreased body-weight gain and food consumption). There is no evidence of increased (quantitative or qualitative) susceptibility in the prenatal developmental toxicity study in rabbits or in the 2-generation reproduction study in rats on 2,4-D. Regarding the 2,4-D amine salt and ester forms, no evidence of increased susceptibility (quantitative or qualitative) was observed in the prenatal developmental toxicity study in rat and rabbits (except for 2,4-D DEA) dosed with any of the amine salts or esters of 2,4-D. There is evidence of increased susceptibility (qualitative) in the prenatal developmental study in rabbits for 2,4-D DEA salt. After establishing developmental toxicity endpoints to be used in the risk assessment with traditional uncertainty factors (10x for interspecies variability and 10x for intraspecies variability), the Agency has no residual concerns for the effects seen in the developmental toxicity studies.

3. *Conclusion*. EPA has concerns with regard to the completeness of the toxicity database. A developmental neurotoxicity (DNT) study in rats is required for 2,4-D. The Agency concluded that there is a concern for developmental neurotoxicity resulting from exposure to 2,4-D. There is evidence of neurotoxicity, including clinical signs such as ataxia and decreased motor activity in pregnant rabbits following dosing during gestation days 6-15 in studies on 2,4-D itself and 2,4-D amine salts and esters, and tremors in dogs that died on test following repeat exposure to 2,4-D. Incoordination and slight gait abnormalities (forepaw flexing or knuckling) were also observed following dosing in the acute neurotoxicity study with 2,4-D. There is also evidence of developmental toxicity, as discussed above. In addition, the Agency determined that a repeat two generation reproduction study using a new protocol is required to address concerns for endocrine disruption (thyroid and immunotoxicity measures). Examination of the existing database does not reveal a basis for concluding that aggregate exposure to 2,4-D will be safe for infants and children in the absence of the additional 10X FQPA safety factor. Therefore, the Agency determined that the 10X FQPA safety factor, in the form of a database uncertainty factor (UFDB), will be retained.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to 2,4-D will occupy 18% (DEEM) of the aPAD for the U.S. population, 43 % (Lifeline) of the aPAD for females 13–49 years old, and 31% (DEEM) of the aPAD for children 1–2 years old.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to 2,4-D from food and drinking water will utilize 10% (DEEM) of the cPAD for the U.S. population, 24% (DEEM) of the cPAD for all Infants (< 1 year old), and 18% (DEEM) of the cPAD for children 1–2 years old. There are no residential uses for 2,4-D that result in chronic residential exposure to 2,4-D.

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

2,4-D is currently registered for use that could result in short-term residential exposure. Short-term aggregate risks were calculated only for females 13–49 and children 1–6 because these population subgroups have the highest exposure and are protective of the other subgroups. The short-term aggregate MOEs are presented in Table 4 of this unit and indicate that the short-term risks are not of concern because the MOEs equal or exceed the target MOE of 1,000.

TABLE 4.—AGGREGATE SHORT-TERM MOES INCLUDING TURF EXPOSURES FOR 2,4-D

Population subgroup	Turf application rate (lbs. (ae)/ai)	Chronic food exposure mg/kg/day)	Short-term turf exposure (mg/kg/day)	Chronic Estimated Drinking Water Concentration (EDWC) (µg/liter)	Drinking water exposure (mg/kg/day)	Aggregate exposure (mg/kg/day)	Aggregate MOE
Females 13–49	1.5	0.000195	0.024	15	0.00050	0.0247	1,000
Children 1–6	1.5	0.000424	0.021	15	0.0010	0.0224	1,100

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

Though residential exposure could occur with the use of 2,4-D, intermediate-term residential risks were not calculated for any of the residential scenarios because there are no intermediate term residential scenarios; residential turf application exposures are expected to be short-term in duration for broadcast treatments because the label allows only two broadcast treatments per year and because 2,4-D dissipates rapidly from the turf after application. The turf transferable residue studies indicated that the 2,4-D half life ranged from less than 1 day to 2.8 days.

5. *Aggregate cancer risk for U.S. population*. The aggregate cancer risk was not calculated for 2,4-D based on the lack of carcinogenicity in a rat carcinogenicity study and a mouse carcinogenicity study. The endpoint selected for cPAD is protective of the possible carcinogenic activity of 2,4-D.

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, and to infants and children from aggregate exposure to 2,4-D residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of 2,4-D in/on various plant and animal commodities. No Codex MRLs have been established, however, for the crops

covered by this tolerance action: Hop, soybean, and wild rice.

C. Conditions

A developmental neurotoxicity study, a subchronic inhalation toxicity study, a repeat 2-generation reproduction study (using the new protocol) addressing concerns for endocrine disruption (thyroid and immunotoxicity measures), grape processing study, wheat hay field trials, and limited irrigated crop studies (sugar beet roots and tops and strawberries) are requested.

D. Response to Comments

Public comments were received from B. Sachau who objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing conducted on animals have absolutely no validity and are cruel to the test animals. B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to 2,4-D, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has responded to B. Sachau's generalized comments on numerous previous occasions. (See the **Federal Register** of January 7, 2005 (70 FR 1349, 1354) (FRL–7691–4) and the **Federal Register** of October 29, 2004 (69 FR 63083, 63096) (FRL–7681–9).

V. Conclusion

Therefore, the tolerance is established for residues of 2,4-D in or on hop at 0.05 ppm, soybean at 0.02 ppm, and wild rice at 0.1 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0038 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 26, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350,1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0038, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to:*opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

Risks (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: July 20, 2005.

Donald R. Stubbs,

Acting 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. Section 180.142 is amended by alphabetically adding commodities to the table in paragraph (a)(2) introductory text and removing and reserving paragraph (a)(11) to read as follows:

§ 180.142 2,4-D; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * *	*
Hop	0.05
* * * *	*
Rice, wild	0.1
* * * *	*
Soybean	0.02
* * * *	*

* * * * *

[FR Doc. 05–14886 Filed 7–26–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0171; FRL–7720–3]

Lignosulfonates; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Agency is establishing 44 exemptions from the requirement of a tolerance for residues of various lignosulfonate chemicals in or on raw agricultural commodities when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, or to animals under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This regulation eliminates the need to establish a maximum permissible level for residues of these lignosulfonate chemicals.

DATES: This regulation is effective July 27, 2005. Objections and requests for hearings must be received on or before September 26, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2005–0171. 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., 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 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.,