

*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.

**VII. 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: August 28, 2006.

**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 180.600 is amended by revising the tolerance levels for wheat, forage in the table in paragraph (a)(1) and for cattle, meat byproducts; goat, meat byproducts; horse, meat byproducts; milk; and sheep, meat byproducts in the table in paragraph (a)(2) to read as follows:

**§ 180.600 Propoxycarbazone; tolerances for residues.**

(a) *General.* (1) \* \* \*

Commodity	Parts per million
Wheat, forage .....	17

Commodity	Parts per million
* * *	* *
(2) * * *	
Commodity	Parts per million
* * *	* *
Cattle, meat byproducts	0.3
* * *	* *
Goat, meat byproducts ...	0.3
* * *	* *
Horse, meat byproducts	0.3
Milk .....	0.03
* * *	* *
Sheep, meat byproducts	0.3
* * *	* *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0664; FRL-8089-3]

**Paraquat Dichloride; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of paraquat dichloride in or on various food and feed commodities. The tolerances were requested by Syngenta Crop Protection Inc. through submission of several pesticide petitions. Syngenta Crop Protection Inc. requested these tolerances 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 September 6, 2006. Objections and requests for hearings must be received on or before November 6, 2006, 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-2006-0664. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The 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:**

Hope Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-305-5410; e-mail address: [johnson.hope@epa.gov](mailto:johnson.hope@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?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, as amended by the 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. 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-2006-0664 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 November 6, 2006.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0664, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for

deliveries of boxed information. The Docket telephone number is (703) 305-5805.

**II. Background and Statutory Findings**

In the **Federal Register** of June 29, 2005 (70 FR 124) (FRL-7718-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1E6332, PP 1E6319, PP 1E6223, PP 2F6433, PP 3E6763) by Syngenta Crop Protection Inc, P.O. Box 18300, Greensboro, NC 27419-8300. The petitions requested that 40 CFR 180.205 be amended by establishing tolerances for residues of the herbicide paraquat dichloride as follows: In or on okra at 0.05 ppm (PP 1E6332); onion (dry bulb) at 0.1 ppm (PP 1E6319); tanager at 0.05 ppm (PP 1E6223); animal feed, nongrass, group at 5.0; barley, hay at 3.0 ppm; barley, straw at 1.0 ppm; beet, sugar, tops at 0.05 ppm; berry group at 0.05 ppm; cattle, kidney at 0.3 ppm; cotton gin byproducts at 82.0 ppm; cotton, seed at 5.0 ppm; cranberry at 0.05 ppm; ; fruit, pome, group at 0.05 ppm; fruit, stone, group at 0.05 ppm; goat, kidney at 0.3 ppm; grape at 0.05 ppm; hog, kidney at 0.3 ppm; hops, cone, dry at 0.5 ppm; horse, kidney at 0.3 ppm; nut, tree, group at 0.05 ppm; pea and bean, dried shelled, except soybean, subgroup at 0.30 ppm; pea and bean, succulent, shelled, subgroup at 0.05 ppm; sheep, kidney at 0.3 ppm; sorghum, forage at 0.1 ppm; soybean, seed at 0.70 ppm; soybean, forage at 0.40 ppm; soybean, hay at 6.0 ppm; soybean, aspirated grain fractions at 60.0 ppm; vegetable, brassica leafy, group at 0.05 ppm; vegetable, cucurbit, group at 0.05 ppm; vegetable, fruiting, group at 0.05 ppm; vegetable, legume, edible-podded, subgroup at 0.05 ppm; wheat, grain at 1.5 ppm; wheat, forage at 0.40 ppm; wheat, hay at 3.0 ppm; wheat, straw at 40.0 ppm; wheat, aspirated grain fractions at 65.0 ppm (PP 2F6433); ginger at 0.1 ppm (PP 3E6763). That notice included a summary of the petition prepared by Syngenta Crop Protection Inc., the registrant. As a result of the review of the residue field trials, the proposed tolerance level for barley, hay was subsequently revised to 3.5 ppm. One comment was received on the notice of filing. EPA’s response to this comment is discussed in Unit IV (C) below.

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 the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

**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 paraquat dichloride on animal feed, nongrass, group 18, forage at 75 ppm; animal feed, nongrass, group 18, hay at 210 ppm; barley, hay at 3.5 ppm; barley, straw at 1.0 ppm; beet, sugar, tops at 0.05 ppm; berry group 13 at 0.05 ppm; cattle, kidney at 0.50 ppm; cotton, gin byproducts at 110 ppm; cotton, undelinted seed at 3.5 ppm; cranberry at

0.05 ppm; fruit, pome, group 11 at 0.05 ppm; fruit, stone, group 12 at 0.05 ppm; ginger at 0.10 ppm; goat, kidney at 0.50 ppm; grain, aspirated fractions at 65 ppm; grape at 0.05 ppm; hog, kidney at 0.50 ppm; hop, dried cones at 0.50 ppm; horse, kidney at 0.50 ppm; nut, tree, group 14 at 0.05 ppm; okra at 0.05 ppm; onion, bulb at 0.10 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean at 0.30 ppm; pea and bean, succulent shelled, subgroup 6B at 0.05 ppm; sheep, kidney at 0.50 ppm; sorghum, forage, forage at 0.10 ppm; sorghum, grain, forage at 0.10 ppm; soybean, forage at 0.40 ppm; soybean, hay at 10 ppm; soybean, hulls at 4.5 ppm; soybean, seed at 0.70 ppm; vegetable, Brassica leafy, group 5 at 0.05 ppm; vegetable, cucurbit, group 9 at 0.05 ppm; vegetable, fruiting, group 8 at 0.05 ppm; vegetable, legume, edible podded, subgroup 6A at 0.05 ppm; wheat, forage at 0.50 ppm; wheat, grain at 1.1 ppm; wheat, hay at 3.5 ppm; and wheat, straw at 50 ppm. Additionally, EPA has determined that the current tolerance with regional registrations for residues of paraquat dichloride on tanager at 0.05 ppm may be extended to the State of Florida. 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

paraquat dichloride as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the index of docket ID number EPA-HQ-OPP-2006-0664.

*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.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for dichloride used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PARAQUAT DICHLORIDE 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 = 1.25 mg/kg/day UF = 300 Acute RfD = 0.0125 mg/kg/day	Special FQPA SF = 1X aPAD = 0.0042 mg/kg/day	Multi-generation rat study LOAEL = 3.75 mg/kg/day based on increased incidences of alveolar histiocytes in both sexes
Acute Dietary (General population including infants and children)	NOAEL = 1.25 mg/kg/day UF = 100 Acute RfD = 0.0125 mg/kg/day	Special FQPA SF = 1X aPAD = 0.0125 mg/kg/day	Multi-generation rat study LOAEL = 3.75 mg/kg/day based on increased incidences of alveolar histiocytes in both sexes
Chronic Dietary (All populations)	NOAEL = 0.45 mg/kg/day UF = 100 Chronic RfD = 0.0045 mg/kg/day	Special FQPA SF = 1X cPAD = 0.0045 mg/kg/day	Chronic toxicity in dogs LOAEL = 0.93 mg/kg/day based on increased severity of chronic pneumonitis and gross lung lesions in both sexes, and focal pulmonary granulomas in males

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PARAQUAT DICHLORIDE 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
Short-Term/Intermediate-Term Dermal (1 day to 6 months)	NOAEL = 1.25 mg/kg/day (dermal absorption factor = 0.3%)	LOC = MOE = 100	Multi-generation rat study LOAEL = 3.75 mg/kg/day based on increased incidences of alveolar histiocytes in both sexes
Long-Term Dermal (> 6 months)	NOAEL = 0.45 mg/kg/day (dermal absorption factor = 0.3%)	LOC = MOE = 100	Chronic toxicity in dogs LOAEL = 0.93 mg/kg/day based on increased severity of chronic pneumonitis and gross lung lesions in both sexes, and focal pulmonary granulomas in males
Short-Term, Intermediate-Term, Long-Term Inhalation (1 to > 6 months)	NOAEL = 0.01 µg/L (inhalation absorption factor = 100%)	LOC = MOE = 100	21-day inhalation toxicity study LOAEL = 0.10 µg/L based on squamous keratinizing metaplasia and hyperplasia of the epithelium of the larynx
Cancer (oral, dermal, inhalation)	Classification: Category E (evidence of non-carcinogenicity to humans)		

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been previously established (40 CFR 180.205) for the residues of paraquat dichloride, in or on a variety of raw agricultural commodities, including egg, milk, and the meat, fat and meat by-products of cattle, goats, hogs, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from paraquat dichloride 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 one-day or single exposure.

The Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and a supplemental children's survey conducted in 1998 and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A partially refined, probabilistic acute dietary exposure assessment using tolerance-level residues for all registered and proposed commodities, maximum estimates of percent crop treated information for some registered commodities, and DEEM default processing factors for some commodities, was conducted for the general U.S. population and various population subgroups. Drinking water was incorporated directly into the dietary assessment using a high-end monitoring value of 1.52 ppb.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A partially refined, chronic dietary exposure assessment using tolerance-level residues for all registered and proposed commodities, average estimates of percent crop treated information for some registered commodities, and DEEM default processing factors for some commodities, was conducted for the general U.S. population and various population subgroups. Drinking water was incorporated directly into the dietary assessment using a high-end monitoring value of 1.52 ppb.

iii. *Cancer.* Paraquat dichloride is a Category E chemical (evidence of non-carcinogenicity to humans).

iv. *Anticipated residue and percent crop treated (PCT) information.* 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; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not underestimate 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:

For the acute assessment, maximum percent crop treated information was used on the following commodities: alfalfa 2.5%, almonds 30%, apples 30%, apricots 20%, artichokes 40%, asparagus 15%, avocados 5%, barley 2.5%, green beans 3%, blackberries 40%, blueberries 15%, broccoli 3%, Brussels sprouts 3%, cabbage 3%, cantaloupes 3%, carrots 3%, cherries 30%, corn 5%, cotton 20%, cucumbers 30%, dry beans/peas 5%, eggplant 20%, figs 10%, garlic 5%, grapefruit 5%, grapes 55%, hazelnuts (filberts) 70%, kiwifruit 3%, lemons 3%, lettuce 3%, nectarines 25%, olives 10%, onions 5%, oranges 10%, peaches 40%, peanuts 35%, pears 15%, green peas 3%, pecans 15%, peppers 30%, pistachios 45%, potatoes 5%, prunes and plums 20%, pumpkins 5%, raspberries 75%, rice 2.5%, safflower 2.5%, sorghum 2.5%, soybeans 2.5%, squash 10%, strawberries 25%, sugar beets 2.5%, sugarcane 5%, sunflowers 2.5%, sweet corn 5%, tangelos 30%, tangerines 10%, tomatoes 15%, walnuts 20%, watermelons 10%, and wheat 2.5%.

For the chronic assessment, average percent crop treated information was

used on the following commodities: alfalfa 1%, almonds 30%, apples 20%, apricots 10%, artichokes 30%, asparagus 10%, avocados 1%, barley 1%, green beans 1%, blackberries 30%, blueberries 10%, broccoli 1%, cabbage 1%, cantaloupes 1%, carrots 1%, cherries 20%, corn 1%, cotton 20%, cucumbers 5%, dry beans/peas 1%, eggplant 20%, figs 10%, garlic 1%, grapefruit 5%, grapes 20%, hazelnuts (filberts) 55%, hops 80%, kiwifruit 1%, lemons 1%, lettuce 1%, nectarines 15%, olives 5%, onions 1%, oranges 5%, peaches 30%, peanuts 25%, pears 10%, green peas 1%, pecans 10%, peppers 10%, pistachios 30%, potatoes 5%, prunes and plums 15%, pumpkins 5%, raspberries 70%, rice 1%, safflower 1%, sorghum 1%, soybeans 1%, squash 5%, strawberries 15%, sugar beets 1%, sugarcane 5%, sunflowers 1%, sweet corn 1%, tangelos 20%, tangerines 5%, tomatoes 5%, walnuts 15%, watermelons 5%, and wheat 1%.

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 5% except for those situations in which the average PCT is less than one. In those cases 1% is used as the average. 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 5%, except for those situations in which the maximum PCT is 2.5%. In those cases, 2.5% is used as the maximum. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

*2. Dietary exposure from drinking water.* Paraquat dichloride undergoes minimal degradation in the environment, and thus is very persistent (as parent). However, its very high propensity to bind to solids, particularly clay, makes it very immobile. In addition, paraquat dichloride does not readily appear to desorb from clay. The greatest cause for concern is likely to be erosion of contaminated sediments off-site and subsequent redeposition onto non-target areas (especially surface water bodies). There is an additional (minor) concern for the one proposed new usage (wheat) that includes aerial

spray; however, this use entails very small amounts (relative to all other uses), so spray drift onto nearby surface water drinking water sources should be fairly limited. Because of its very low mobility and strong tendency to bind tightly to soils, paraquat dichloride contamination of drinking water supplies derived from groundwater is expected to be highly unlikely. In addition, the strong binding characteristics of paraquat dichloride are likely to render most residues in raw drinking water sources removable through sedimentation processes, which are typically included as part of standard drinking water treatments.

Because of its strong cation-exchange sorption to soils, modeling is not appropriate for paraquat dichloride. In most circumstances, the levels of paraquat dichloride residues in surface or ground water are expected to be insignificant. Because it should sorb to suspended sediment, coagulation and flocculation processes in drinking water treatment plants are likely to remove any paraquat dichloride residues present in the raw water. Residues of paraquat dichloride in drinking water derived from surface supplies can therefore be assumed to be negligible. For residues in ground water however, the EPA used the value of 1.52 ppb reported in Virginia, for human exposure assessment, as this represents a high-end, but not worst-case value from the available monitoring data. As a result, the groundwater monitoring value of 1.52 ppb was used for both the acute and chronic analyses. This estimate of drinking water concentration was directly entered into the dietary exposure model (DEEM-FCID™).

*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).

Paraquat dichloride is not registered for use on any sites that would result in residential exposure.

*4. Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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 paraquat dichloride and any other substances and paraquat dichloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that paraquat dichloride 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 Office of Pesticide Programs 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 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors 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.* Prenatal developmental studies in rats and mice show that developmental effects only occur in the presence of maternal toxicity. No effect on reproduction was observed. Fetal effects were limited to delayed ossification and decreased body weights. There was no indication from these studies that paraquat dichloride is involved in endocrine disruption.

*3. Conclusion.* The toxicological database for paraquat dichloride is incomplete, lacking an acceptable prenatal developmental study in a non-rodent species. However, four acceptable developmental studies in rats and mice have been submitted for paraquat dichloride, and the Agency

considers the toxicology database adequate for hazard characterization, and to address FQPA concerns. The Agency is retaining a 3x uncertainty factor for the acute dietary subpopulation Females 13-49 years old because of residual concerns for developing fetuses. All other populations will have a 1x safety factor. The FQPA safety factor was reduced to (1x) for the following reasons:

- (i) There is no evidence of neurotoxicity;
- (ii) There is no indication of quantitative or qualitative increased

susceptibility of rats or mice to *in utero* and/or prenatal/postnatal exposure of rats;

- (iii) The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children; and
- (iv) There are no registered residential uses of paraquat dichloride.

*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 paraquat dichloride will occupy 33% of the aPAD for the U.S. population, 54% of the aPAD for females 13-49 years old, 52% of the aPAD for all infants (<1 year old), and 66% of the aPAD for children 1-2 years old. Acute aggregate risk consists of risks resulting from exposure to residues in food and drink water only. The acute dietary exposure analysis included both food and drinking water, and as a result, the acute aggregate risk assessment is equivalent to the acute dietary analysis.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PARAQUAT DICHLORIDE

Population Subgroup	Dietary Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.004064	33
All Infants (<1 year old)	0.006550	52
Children 1-2 years old	0.008240	66
Females 13-49 years old	0.002284	54

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to paraquat dichloride from food will utilize 8% of the cPAD for the U.S. population, 13% of the cPAD for all infants (<1 year old), and

26% of the cPAD for children 1-2 years old. There are no residential uses for paraquat dichloride that result in chronic residential exposure to paraquat dichloride. Chronic aggregate risk consists of risks resulting from exposure to residues in food and drink water

only. The chronic dietary exposure analysis included both food and drinking water, and as a result, the chronic aggregate risk assessment is equivalent to the chronic dietary analysis.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PARAQUAT DICHLORIDE

Population/Subgroup	Dietary Exposure (mg/kg/day)	%/cPAD
General U.S. Population	0.000353	8
All Infants (<1 year old)	0.000584	13
Children 1-2 years old	0.001175	26
Females 13-49 years old	0.000250	6

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).

Paraquat dichloride is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

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).

Paraquat dichloride is not registered for use on any sites that would result in

residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Paraquat dichloride is a Category E chemical (evidence of non-carcinogenicity in humans). As a result, an aggregate cancer risk assessment was not conducted.

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 paraquat dichloride residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology is available to enforce the tolerance expression. Method I of Pesticide Analytical Manual (PAM), Volume II (spectrophotometric), is adequate for plant tolerance enforcement purposes. In addition, Method 1B (spectrophotometric) has also been found to adequately recover paraquat cation residues. Method IA of PAM Volume II (spectrophotometric) is available for animal tolerance enforcement purposes. Method 4B of PAM Volume II (HPLC) is also available for animal tolerance enforcement purposes.

Adequate enforcement methodology (specify method; example—gas chromatography) 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](mailto:residuemethods@epa.gov).

#### B. International Residue Limits

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for paraquat dichloride residues in various commodities. The Codex and U.S. tolerances are in harmony with respect to MRL/tolerance expression; both regulate the parent paraquat cation only. Compatibility between U.S. tolerances and Codex MRLs exists for eggs, passion fruit, sunflower seed, and vegetables [including Brassica leafy vegetables, carrots, cassava, corn (sweet), edible podded legume vegetables, fruiting vegetables, lettuce, onions (green), pigeon peas, turnips (roots and tops), and yams], milk and ruminant tissue, and poultry eggs. Incompatibilities of U.S. tolerances and Codex MRLs on the following raw plant commodities remain because of differences in agricultural practices: cotton seed, dry hops, maize, olives, sorghum, dry soya bean and certain vegetables (such as bulb onion). No Canadian or Mexican MRLs have been established for paraquat dichloride.

#### C. Response to Comments

Several comments were received from a private citizen objecting to pesticide body load, IR-4 profiteering, animal testing, establishing tolerances, and pesticide residues. The Agency has received these same comments from this commenter on numerous previous occasions. Refer to the following **Federal Register** cites: 70 FR 37686, June 30, 2005; 70 FR 1354, January 7, 2005; 69 FR 63096–63098, October 29, 2004; for the Agency's response to these objections.

#### V. Conclusion

Therefore, tolerances are established for residues of paraquat dichloride in or on animal feed, nongrass, group 18, forage at 75 ppm; animal feed, nongrass, group 18, hay at 210 ppm; barley, hay at 3.5 ppm; barley, straw at 1.0 ppm; beet, sugar, tops at 0.05 ppm; berry group 13 at 0.05 ppm; cattle, kidney at 0.50 ppm; cotton, gin byproducts at 110 ppm; cotton, undelinted seed at 3.5 ppm; cranberry at 0.05 ppm; fruit, pome, group 11 at 0.05 ppm; fruit,

stone, group 12 at 0.05 ppm; ginger at 0.10 ppm; goat, kidney at 0.50 ppm; grain, aspirated fractions at 65 ppm; grape at 0.05 ppm; hog, kidney at 0.50 ppm; hop, dried cones at 0.50 ppm; horse, kidney at 0.50 ppm; nut, tree, group 14 at 0.05 ppm; okra at 0.05 ppm; onion, bulb at 0.10 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean at 0.30 ppm; pea and bean, succulent shelled, subgroup 6B at 0.05 ppm; sheep, kidney at 0.50 ppm; sorghum, forage, forage at 0.10 ppm; sorghum, grain, forage at 0.10 ppm; soybean, forage at 0.40 ppm; soybean, hay at 10 ppm; soybean, hulls at 4.50 ppm; soybean, seed at 0.70 ppm; vegetable, Brassica leafy, group 5 at 0.05 ppm; vegetable, cucurbit, group 9 at 0.05 ppm; vegetable, fruiting, group 8 at 0.05 ppm; vegetable, legume, edible podded, subgroup 6A at 0.05 ppm; wheat, forage at 0.50 ppm; wheat, grain at 1.1 ppm; wheat, hay at 3.5 ppm; and wheat, straw at 50 ppm..

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions 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.

**VII. 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: August 25, 2006.

**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 § 180.205, the table to paragraph (a) is amended as follows:

a. By adding entries for animal feed, nongrass, group 18, forage; animal feed, nongrass, group 18, hay; barley, hay; barley, straw; berry, group 13; cotton, gin byproducts; cranberry; fruit, pome group 11; fruit, pome group 12; grain, aspirated fractions; ginger; grape; okra; nut, tree, group 14; onion, bulb; pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean; pea and bean, succulent shelled, subgroup 6B; sorghum, forage, forage; sorghum, grain, forage; soybean, hay; soybean, hulls; soybean, seed; vegetable, Brassica leafy, group 5; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; vegetable, legume, edible podded, subgroup 6A; wheat, forage; wheat, hay; and wheat, straw.

b. By revising the entries for beet, sugar, tops; cattle, kidney; cotton,

undelinted seed; goat, kidney; hog, kidney; hop, dried cone; horse, kidney; sheep, kidney; soybean, forage; and wheat, grain.

c. By removing from the table in paragraph (a) the entries for onion, dry bulb; sorghum, forage; and vegetable, fruiting.

**§ 180.205 Paraquat; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	*
Animal feed, nongrass, group 18, forage	75
Animal feed, nongrass, group 18, hay	210
Barley, hay	3.5
Barley, straw	1.0
Beet, sugar, tops	0.05
Berry group 13	0.05
Cattle, kidney	0.50
Cotton, gin byproducts	110
Cotton, undelinted seed	3.5
Cranberry	0.05
Fruit, pome, group 11	0.05
Fruit, pome, group 12	0.05
Ginger	0.10
Goat, kidney	0.50
Grain, aspirated fractions	65
Grape	0.05
Hog, kidney	0.50
Hop, dried cones	0.50
Horse, kidney	0.50
Nut, tree, group 14	0.05
Okra	0.05
Onion, bulb	0.10
Pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean	0.30
Pea and bean, succulent shelled, subgroup 6B	0.05
Sheep, kidney	0.50
Sorghum, forage, forage	0.10
Sorghum, grain, forage	0.10
Soybean, forage	0.40
Soybean, hay	10
Soybean, hulls	4.5
Soybean, seed	0.70
Vegetable, Brassica leafy, group 5	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.05

Commodity	Parts per million
Vegetable, legume, edible podded, subgroup 6A	0.05
Wheat, forage	0.50
Wheat, grain	1.1
Wheat, hay	3.5
Wheat, straw	50

\* \* \* \* \*

[FR Doc. E6-14642 Filed 9-5-06; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 710**

[EPA-HQ-OPPT-2005-0059; FRL-7752-8]

RIN 2070-AC61

**TSCA Inventory Update Reporting Rule; Electronic Reporting**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to amend the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Reporting (IUR) regulations to allow the electronic submission of information and to make several minor corrections. For the first time, in 2006, reporters of IUR data will be able to use the Internet, through EPA's Central Data Exchange (CDX), to submit information on their chemicals to EPA. In addition, EPA will continue to allow IUR submissions either on CD ROM or on paper. EPA is also correcting two paragraph cross-references and a section heading. Additionally, EPA is clarifying requirements for the reporting of company identification information.

**DATES:** This direct final rule is effective on November 6, 2006 without further notice, unless EPA receives adverse comment by October 6, 2006. If, however, EPA receives adverse comment, EPA will publish a **Federal Register** document to withdraw the portion of the rule that relates to the specific comment that was made before the effective date of the direct final rule. The remainder of the rule will become effective on November 6, 2006.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2005-0059, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Document Control Office (7407M), Office of Pollution Prevention