Commodity	Parts per million
Acerola	2.0
* * * * *	
Atemoya	2.0
Avocado	2.0
* * * * *	
Biriba	2.0
Brassica, leafy greens, subgroup	25
Bushberry subgroup	3.0
Canistel	2.0
* * * * *	
Cherimoya	2.0
* * * * *	
Custard apple	2.0
Eggplant	2.0
Feijoa	2.0
* * * * *	
Grass, forage[1]	15
Grass, hay[1]	20
Guava	2.0
* * * * *	
Ilama	2.0
Jaboticaba	2.0
Jackfruit	2.0
Juneberry	3.0
Lingonberry	3.0
Longan	2.0
Loquat	2.0
Lychee	2.0
Mango	2.0
Okra	2.0
Passion fruit	2.0
Pawpaw	2.0
Papaya	2.0
* * * * *	
Pepper	2.0
Peppermint, tops	30
Persimmon	2.0
* * * * *	
Pulasan	2.0
Rambutan	2.0
* * * * *	
Salal	3.0
Sapodilla	2.0
Sapote, black	2.0
Sapote, mamey	2.0
Sapote, white	2.0
Soursop	2.0
* * * * *	
Spanish lime	2.0
Spearmint, tops	30
Star apple	2.0
Starfruit	2.0
* * * * *	
Strawberry	10
Sugar apple	2.0
Tamarind	2.0
* * * * *	
Turnip, tops	25
* * * * *	
Watercress	3.0
Wax jambu	2.0

Commodity	Parts per million
*	* * * *

[1] There are no U.S. registrations for rangeland or pasture grass.

* * * * *

[FR Doc. 01–23607 Filed 9–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301178; FRL–6799–2]

RIN 2070–AB78

Paraquat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of paraquat in or on dry pea; endive; field corn grain, forage and stover; pop corn grain and stover; globe artichoke; and persimmon. The Interregional Research Project Number 4 (IR-4) and Zeneca Ag. Products requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This final rule establishes permanent tolerances for paraquat and as part of that process the Agency has reassessed existing tolerances. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. All permanent tolerances for paraquat that existed on August 2, 1996, were previously reassessed by the Paraquat Dichloride Reregistration Eligibility Document signed September 30, 1996. Consequently, regarding the actions in this final rule, no tolerance reassessments are counted toward the August 2002 review deadline of FFDCA section 408(q).

DATES: This regulation is effective September 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301178, must be received by EPA on or before November 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301178 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; and e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules'', and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/

opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301178. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 7, 1998 (63 FR 53902) (FRL–6026–3), December 3, 1999 (64 FR 67905) (FRL–6392–6), and June 21, 2000 (65 FR 38535) (FRL–6558–9), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of pesticide petitions (PP) for a tolerance by the IR-4, 681 U.S. Highway # 1 South, North Brunswick, NJ 08902–3390 and Zeneca Ag. Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458. These notices included summaries of the petitions prepared by Zeneca Ag. Products, the registrant. There were no comments received in response to the notice of filings.

The petitions requested that 40 CFR 180.205 be amended by establishing tolerances for residues of the desiccant, defoliant and herbicide paraquat, 1,1′-dimethyl-4,4′-bipyridinium-ion, derived from application of the dichloride salt (calculated as the cation), in or on various food commodities, as follows:

1. PP 5F1625, submitted by Zeneca Ag. Products, proposed tolerances for field corn and pop corn grain at 0.05 part per million (ppm); field corn and pop corn forage at 3.0 ppm; field corn and pop corn stover at 10.0 ppm. The proposed tolerance for field corn and pop corn grain was increased to 0.1 ppm to harmonize with the Codex maximum residue limit (MRL) of 0.1 ppm for maize.

2. Food additive petition 5H5088, submitted by Zeneca Ag. Products, proposed a food additive tolerance for corn flour at 0.1 ppm. The proposed tolerance for corn flour was subsequently withdrawn since EPA determined that the tolerance for field corn grain at 0.1 ppm is adequate to cover residues in corn flour.

3. PP 1E4019, submitted by IR-4, proposed a tolerance for globe artichoke at 0.05 ppm.

4. PP 9E6026, submitted by IR-4, proposed a tolerance for endive at 0.05 ppm.

5. PP 7E4857, submitted by IR-4, proposed a tolerance with regional registration for dry pea at 0.3 ppm. IR-4 proposed that registration be geographically limited based on the geographical representation of the available residue data (residue data submitted by IR-4 for dry peas are from Washington and Idaho). EPA concluded that there is no need to regionally restrict the registration for dry peas since there is available residue data for dry beans, which also have a tolerance at 0.3 ppm for a similar use of paraquat.

6. 9E6009, submitted by IR-4, proposes a tolerance for persimmon at 0.05 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 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), 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), for tolerances for residues of paraquat on dry pea; endive; field corn grain, forage and stover; pop corn grain and stover; globe artichoke; and persimmon. EPA's assessment of exposures and risks associated with establishing the tolerances 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. The nature of the toxic effects caused by paraquat are discussed in the following Table 1 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.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3150	Subchronic in nonrodents (dogs)	NOAEL = 0.5 mg/kg/day LOAEL = 1.5 mg/kg/day based on increased absolute and relative lung weight, alveolitis and alveolar collapse.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3250	Subchronic dermal toxicity (rabbits)	NOAEL = 1.15 mg/kg/day LOAEL = 2.6 mg/kg/day based on scabbing at the dosing site.
870.3465	Subchronic inhalation toxicity (rats)	NOAEL = 0.01 μg/L LOAEL = 0.1 μg/L based on nasal discharge and squamous keratinizing metaplasia, and/or hyperplasia of the epithelium of the larynx.
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL = 3 mg/kg/day Maternal LOAEL = 5 mg/kg/day based on death occurred in 2 of 30 rats at 5 mg/kg/day and 6 of 30 at 10 mg/kg/day. Developmental NOAEL = 1 mg/kg/day Developmental LOAEL = 5 mg/kg/day based on delayed ossification.
870.3700	Prenatal developmental in rodents (Alderley Park mice)	Maternal NOAEL = 1 mg/kg/day Maternal LOAEL = 5 mg/kg/day based on reduction in body weight gain. Developmental NOAEL = 1 mg/kg/day Developmental LOAEL = 5 mg/kg/day based on based on partial ossified 4th sternebrae.
870.3800	Reproduction and fertility effects (Wistar-derived Alderley Park strain of rats)	Parental/Systemic NOAEL = 1.25 mg/kg/day Parental/Systemic LOAEL = 3.75 mg/kg/day based on increased incidence of alveolar histiocytes . Reproductive NOAEL ≥ 7.5 mg/kg/day
870.4100	Chronic toxicity/carcinogenicity rodents (Fisher 344 rats)	NOAEL = 1.25 mg/kg/day LOAEL = 3.75 mg/kg/day based on increased incidence of opacities/cataracts in males, ptosis/swollen eyelids in females, and non-neoplastic lung lesions in male non-survivors.
870.4100	Chronic toxicity/carcinogenicity rodents (Wistar rats)	NOAEL = 4.15 mg/kg/day LOAEL = 12.25 mg/kg/day based on increased mortality in males and females; decreased erythrocytes, hemoglobin, and serum protein in males and females; decreased hematocrit, glucose and corpuscular cholinesterase activity in males; decreased leucocytes, albumin/globulin ratio and alkaline phosphatase, glutamic-oxaloacetic transaninase, and glutamic-pyruvic transaminase activities in females; increased polymorphonucleocytes in males; increased potassium and glucose in females; decreased absolute and/or relative weights of heart in males and females, and liver and brain in females; and decreased absolute weights of kidneys in males and females and ovaries.
870.4100	Chronic toxicity (dogs)	NOAEL = 0.45 mg/kg/day LOAEL = 0.93 mg/kg/day based on a dose-related increase in severity and extent of chronic pneumonitis.
870.1000	Gene mutation	Not mutagenic in *Salmonella typhimurium* assay or genotoxic in the Unscheduled DNA synthesis assay *in vivo* or *in vitro*.
870.5375	Cytogenetics	In structural chromosomal aberration tesing using human lymphocytes, the results were weakly positive and the sister chromatid exchange assay was positive. Paraquat was negative for chromasomal aberration in the bone marrow test system and there was no evidence of suppress fertility or dominant lethal mutagenicity in mice.

B. Toxicological Endpoints

The dose at which 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 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.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, 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 FQPA 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 is expressed as 1×10^{-6} or one in a million). 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 paraquat used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PARAQUAT FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = 1.25 mg/kg/day UF = 100 Acute RfD = 0.0125 mg/kg/day	FQPA SF = 3X aPAD = acute RfD ÷ FQPA SF = 0.0042 mg/kg/day	3–Generation reproduction study in rats LOAEL = 3.75 mg/kg/day based on increased incidence of alveolar histiocytes.
Acute dietary (general population including infants and children)	NOAEL = 1.25 mg/kg/day UF = 100 Acute RfD = 0.0125 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.0125 mg/kg/day	3–Generation reproduction study in rats LOAEL = 3.75 mg/kg/day based on increased incidence of alveolar histiocytes
Chronic dietary (all populations)	NOAEL = 0.45 mg/kg/day UF = 100 Chronic RfD = 0.0045 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.0045 mg/kg/day	1–Year feeding study in dogs LOAEL = 0.93 mg/kg/day based on increase in severity and extent of chronic pneumontis
Short- and intermediate - term dermal	Oral study NOAEL = 1.25 mg/kg/day (dermal absorption rate = 0.3%)	LOC for MOE = 100 (residential)	3–Generation reproduction study in rats LOAEL = 3.75 mg/kg/day based on increased incidence of alveolar histiocytes
Long-term dermal (several months to lifetime)	Oral study NOAEL = 0.45 mg/kg/day (dermal absorption rate = 0.3% when appropriate)	LOC for MOE = 100 (residential)	1–Year feeding study in dogs LOAEL = 0.93 mg/kg/day based on increase in severity and extent of chronic pneumonitis
Inhalation (any time period)	Inhalation study NOAEL = 0.01 mg/kg/day (respirable particle)	LOC for MOE = 100 (residential)	21–Day inhalation study LOAEL = 0.1 mg/kg/day based on squamous keratinizing metaplasia and/or hyperlasia of the epithelium of the larynx; increased incidence of alveolar histocytes.
Inhalation (any time period)	Oral study NOAEL = 1.25 mg/kg/day (nonrespirable particles)	LOC for MOE = 100 (residential)	3–Generation reproduction study LOAEL = 3.75 mg/kg/day based on increased incidence of alveolar histiocytes
Cancer (oral, dermal, inhalation)	Not applicable	Classified as not likely to be a human carcinogen	

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.205) for the residues of paraquat in or on a variety of raw agricultural commodities, including the meat, fat, and meat by-products of cattle, goats, hogs, horses and sheep and milk. Tolerances are

established for corn grain, forage and fodder at 0.05 (negligible) to cover residues from the preplant use of paraquat on corn. Risk assessments were conducted by EPA to assess dietary exposures from paraquat in food as follows:

i. *Acute exposure*. Acute dietary 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. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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 acute exposure assessments: The acute exposures are based on tolerance level residues and some percent crop treated (PCT) refinement.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic exposures are based on tolerance level residues and some PCT refinement.

iii. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(F) 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 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), EPA may require registrants to submit data on PCT.

The Agency used maximum PCT information as follows: apples 48%; apricots 8%; asparagus 21%; avocados 3%; dry beans 3%, succulent beans 0.6%; bell peppers 40%; berry 14%; blackberry 48%; blueberry 12%; cabbage 4%; carrot 2%; cauliflower 2%; cherries 46%; citrus 13%; cole crops 2%; cucumber (fresh) 11%, cucumber (processed) 10%; eggplant 60%; filbert 14%; table grape 40%, wine grape 28%, other grapes 36%; honeydew melon 6%; leafy vegetables 0.5%; other lettuce 4%; lemon 2%; cantaloupe 7%; melon 5%; nectarine 35%; olives 14%; onion 3%; orange 9%; green pea 0.3%; peach 38%; pear 28%; peppers 36%; pistachio 7%; plum 47%; pome fruit 5%; potato 5%; prune 14%; pumpkins 7%; raisin 21%; raspberry 80%; root and tuber vegetables 0.8%; squash 39%; stone fruit 12%; strawberry 15%; sunflower 2%; sweet corn 2%; tomato (fresh) 34%, tomato (processed) 11%, tomato 25%; almonds 24%; pecan 14%; walnut 29%; other tree nut 13%; other vegetables 21%; and watermelon 4%.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. 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, 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 paraquat may be applied in a particular area.

2. *Dietary exposure from drinking water*. Paraquat is persistent, but is expected to be mostly inactivated by rapid cation exchange to binding sites on soil (especially clay) particles in the environment. Under most circumstances paraquat is unlikely to infiltrate past the first few centimeters of soil, or to move off-field dissolved in runoff. However, detections were reported in household wells at concentrations ranging up to 1.52 µg/L.

Because of its strong cation-exchange sorption to soils, modeling is not appropriate for paraquat dichloride. It should sorb to suspended sediment, and coagulation and flocculation processes in drinking water treatment plants are likely to remove any paraquat residues present in the raw water. Residues of paraquat in drinking water derived from surface supplies can therefore be assumed to be negligible. For residues in ground water however, EPA is using the value of 1.52 µg/L, for acute and chronic human exposure assessment, as this represents a high-end, but not worst-case value from the available monitoring data.

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

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

EPA does not have, at this time, available data to determine whether paraquat has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, paraquat 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 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 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 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.

2. *Prenatal and postnatal sensitivity.* There is no indication of quantitative or qualitative increased susceptibility of rats or mice to *in utero* and/or prenatal/postnatal exposure to rats.

3. *Conclusion.* An FQPA safety factor is necessary for paraquat since there is a data gap for a prenatal developmental study conducted in a non-rodent species. The safety factor was reduced to 3x for paraquat because: (i) There is no indication of quantitative or qualitative increased susceptibility of rats or mice to *in utero* and/or prenatal/postnatal exposure to rats; (ii) EPA determined that a developmental neurotoxicity study is not required; (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. The FQPA safety factor for paraquat is applicable to the females 13–50 years of age population subgroup for acute dietary risk assessment only (there are no residential uses). The safety factor was reduced to 1x for all other exposures and population subgroups.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to paraquat will occupy 32% of the aPAD for the U.S. population, 55% of the aPAD for females 13 years and older, 45% of the aPAD for infants, and 76% of the aPAD for children 1 to 6 years of age. In addition, there is potential for acute dietary exposure to paraquat in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PARAQUAT

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.0125	32	1.52	300
Females (13 to 50 years of age)	0.0042	55	1.52	57
Children (1 to 6 years of age)	0.0125	76	1.52	30

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to paraquat from food will utilize 6% of the cPAD for the U.S. population, 10% of the cPAD for infants, and 16% of the cPAD for children 1 to 6 years of age. There are no residential uses for paraquat that result in chronic residential exposure. In addition, there is potential for chronic dietary exposure to paraquat in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PARAQUAT

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0045	6	1.52	150
Females (13 to 50 years of age)	0.0045	4	1.52	130
Children (1 to 6 years of age)	0.0045	16	1.52	38

3. *Short-, intermediate-, and long-term risk*. Short- intermediate-, and long-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Paraquat 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 do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. Paraquat has been classified as ''not likely to be carcinogenic in humans'' based on the results of carcinogenicity studies in animals. Therefore, paraquat is not expected to pose a cancer risk to humans.

5. *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 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.

B. International Residue Limits

There are no Codex, Canadian or Mexican MRLs for residues of paraquat on dry peas. There is a Codex MRL for ''vegetable (except as otherwise listed)'' at 0.05 ppm and there is a Canadian MRL on peas at 0.1 ppm. Based on the residue observed in dry peas from the proposed use, the U.S. tolerance cannot be harmonized with the Codex vegetable MRL.

There is a Codex MRL for maize at 0.1 ppm defined as the paraquat cation (generally available as dichloride), a Canadian MRL for corn at 0.1 ppm defined as the 1,1′-dimethyl-4,4′-bipyridinium salt, and a Mexican MRL for maize at 0.05 ppm defined as paraquat. The field corn grain tolerance recommended in this assessment matches the 0.1 ppm Codex maize MRL. Domestic tolerances are defined as the paraquat ion, which is in harmonization with international definitions. There are no Codex, Canadian or Mexican MRLs for paraquat on endive, persimmons, or globe artichokes.

V. Conclusion

Therefore, the tolerances are established for residues of paraquat in or on, dry pea at 0.3 ppm; field and pop corn grain at 0.1 ppm; field corn forage at 3.0 ppm; field and pop corn stover at 10.0 ppm; endive at 0.05 ppm; globe artichoke at 0.05 ppm; and persimmon at 0.05 ppm.

VI. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301178 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 20, 2001.

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 issues(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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to

the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *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 Unit I.B.2. Mail your copies, identified by docket control number OPP–301178, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) 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 other 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 FFDCA section 408(d), such as the tolerances 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General

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: September 10, 2001.

Peter Caulkins,

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), 346(a) and 371.

2. Section 180.205 is amended as follows:

i. By alphabetically adding the commodities artichoke, globe; corn, field, forage; corn, field grain; corn, field stover; corn, pop, grain; corn, pop, stover; endive; pea, dry; and persimmon to the table in paragraph (a).

ii. By removing the entries for corn grain, corn fodder, and corn forage from the table in paragraph (a).

iii. By removing the entries for corn flour, corn fodder, corn forage, corn grain and peas (dry) from the table in paragraph (b).

§ 180.205 Paraquat; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
*	* * * * *
Artichoke, globe	0.05
*	* * * * *
Corn, field, forage	3.0
Corn, field, grain	0.1
Corn, field, stover	10.0
*	* * * * *
Corn, pop, grain	0.1
Corn, pop, stover	10.0
*	* * * * *
Endive	0.05
*	* * * * *
Pea, dry	0.3
*	* * * * *
Persimmon	0.05
*	* * * * *

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[FR Doc. 01–23606 Filed 9–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301173; FRL–6801–8]

RIN 2070–AB78

Sulfosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sulfosate (the trimethylsulfonium salt of glyphosate, also known as glyphosate-trimesium) in or on cotton, gin by-products, cotton undelinted seed, dried shelled pea and bean (except soybean) subgroup, edible podded legume vegetable subgroup, fruiting vegetable group, grain sorghum forage, grain sorghum grain, grain sorghum stover, leaves of root and tuber vegetable (except radish) subgroup, pistachio, radish roots, radish tops, succulent shelled pea and bean subgroup, sweet corn forage, sweet corn kernals plus cob with husks removed, sweet corn stover, tuberous vegetable and corm subgroup, and vegetable root (except radish) subgroup. This regulation increases tolerances in wheat bran, wheat grain, wheat hay, wheat shorts, wheat straw, and poultry meat by-products. Zeneca Ag. Products, now Syngenta Crop Protection, requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301173 must be received by EPA on or before November 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301173 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 703–305–5697; and e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301173. The official record consists of the documents specifically referenced in this action, and other