Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(381)(i) (J), (c)(388)(i)(F), (c)(404)(i)(B), and (c)(411) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(381) * * *

(i) * * *

(J) San Diego Air Pollution Control District.

(*1*) Rule 66.1, ''Miscellaneous Surface Coating Operations and Other Processes Emitting Volatile Organic Compounds,'' adopted on February 24, 2010.

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(388) * * *

(i) * * *

(F) Mojave Desert Air Quality Management District.

(*1*) Rule 1116, ''Automotive Refinishing Operations,'' amended on August 23, 2010.

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(404) * * *

(i) * * *

(B) Northern Sierra Air Quality Management District.

(*1*) Rule 228, ''Surface Coating of Metal Parts and Products,'' amended on April 25, 2011.

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(411) New and amended regulations for the following APCDs were submitted on February 23, 2012.

(i) Incorporation by reference.

(A) Sacramento Metropolitan Air Quality Management District.

(*1*) Rule 459, ''Automotive, Mobile Equipment, and Associated Parts and Components Coating Operations,'' amended August 25, 2011.

[FR Doc. 2012–19318 Filed 8–8–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0637; FRL–9357–1]

Paraquat Dichloride; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of paraquat dichloride (hereafter in this document referred to solely as paraquat) in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 9, 2012. Objections and requests for hearings must be received on or before October 9, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2010–0637, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: 703–308–9367; email address: *ertman.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0637 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 9, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0637, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket,

along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 27, 2010 (75 FR 66092) (FRL–9218–2), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E7748) by IR–4 Project Headquarters, Rutgers, the State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.205 be amended by establishing tolerances for residues of the dessicant, defoliant, and herbicide paraquat dichloride, (1,1′-dimethyl-4,4′-bipyridinium-ion) derived from application of either the bis(methyl sulfate) or the dichloride salt (both calculated as the cation), in or on the following perennial tropical and subtropical fruit trees: Sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, lychee, longan, Spanish lime, rambutan, pulasan, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, feijoa, jaboticaba, wax jambu, starfruit (carambola), pawpaw, pomegranate, and white sapote at 0.05 parts per million (ppm). That notice referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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. * * *''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 for paraquat including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with paraquat 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.

Paraquat is severely toxic following acute exposure via the dermal and inhalation routes and only slightly less toxic by the oral route of exposure. It is a dermal and ocular irritant but is not a skin sensitizer.

The primary target organ of paraquat is the lung. Evidence of lung inflammation, scarring, and compromised lung function in response to paraquat are observed throughout the toxicity database in different species (rats, mice, and dogs). Effects in the respiratory tract are observed after acute, subchronic, and chronic exposures regardless of the route of exposure (oral or inhalation). However, inhalation was a more sensitive route of exposure than the oral route. With increasing durations of exposure, effects of paraquat in other organ systems are observed. These effects include liver inflammation and necrosis in rats and inflammation and necrosis of the kidneys in rats and mice. Lenticular changes in the eyes of rats were also observed with increasing durations of exposure. Importantly, the lung effects occur at doses lower than effects in these other organs systems, and so protecting for lung effects protects for all other adverse effects of paraquat.

The effects of paraquat in lungs are considered systemic effects. There are no dermal toxicity studies suitable for evaluation of systemic lung effects in the toxicity database for paraquat. Therefore, the Agency is using a dermal absorption factor of 0.3%, which was derived from dermal absorption studies conducted in humans and monkeys and an oral endpoint for dermal risk assessments.

Paraquat does not cause reproductive toxicity. Developmental toxicity in response to paraquat, when observed, always occurred in the presence of maternal toxicity. Four developmental toxicity studies (two in rats and two in mice) are available. Since effects in the offspring (e.g., reduced body weight/gain and delayed skeletal ossification), when present, were lesser in severity than those observed in maternal animals (e.g., respiratory distress, reduced body weight, lesions in the lungs and kidneys) and were also consistent with those commonly observed as secondary to maternal toxicity, the Agency has concluded that there was no evidence of qualitative susceptibility in the young.

Previously, the Agency had required that a developmental toxicity study in rabbits be conducted for paraquat. As a result, the Food Quality Protection Act (FQPA) Safety Factor (SF) had been retained as a 3X database uncertainty factor for Females 13–39 years old for the acute dietary risk assessment only. The Agency recently reviewed the toxicity database for paraquat and concluded that a developmental toxicity study in rabbits was not likely to add information that would impact the paraquat risk assessment. Therefore, this study is no longer required and the FQPA Safety Factor has been reduced to 1X for this population.

No evidence of neurotoxicity was observed in acute and subchronic neurotoxicity studies conducted with paraquat up to the doses at which respiratory effects were observed (e.g. the maximum tolerated dose). There was also no evidence of immunotoxicity in response to paraquat.

Based on the lack of evidence of carcinogenicity in mice and rats, the Agency has concluded that there is no concern for the carcinogenic potential of paraquat. Paraquat was not mutagenic in the *Salmonella typhimurium* assay, was not genotoxic in the unscheduled DNA synthesis assay *in vitro* or *in vivo,* was negative for chromosomal aberration in the bone marrow test, and no evidence was found for suppressed fertility or dominant lethal mutagenicity in mice. Conversely, paraquat was found to be weakly positive in the mouse lymphoma assay and human lymphocyte cytogenetic assay, and was positive in the sister chromatid exchange assay.

Specific information on the studies received and the nature of the adverse effects caused by paraquat 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 document ''Paraquat Dichloride. Human Health

Risk Assessment for the Request to Add Uses on Perennial Tropical and Sub-Tropical Fruit Trees'' on pps. 31–35 in docket ID number EPA–HQ–OPP–2010–0637.

B. Toxicological Points of Departure/ Levels of Concern

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

A summary of the toxicological endpoints for paraquat used for human risk assessment is shown in the following table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PARAQUAT FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment (in mg/kg/day)	Study and toxicological effects
Acute dietary (all populations)	NOAEL = 1.25 mg/ kg/day. UF_A = 10xUF_H = 10xFQPA SF = 1x	aRfD = 0.0125 ..... aPAD = .0125	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_A = 10x UF_H = 10x FQPA SF = 1x	cRfD = 0.0045 ..... cPAD = .0045	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.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to paraquat, EPA considered exposure under the petitioned-for tolerances as well as all existing paraquat tolerances in 40 CFR 180.205. EPA assessed dietary exposures from paraquat in food as follows:

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

Such effects were identified for paraquat. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the acute analysis assumed a distribution of residues based on tolerance level residues. Empirical and Dietary Exposure Evaluation Model (DEEM) default processing factors were used to modify the field trial data. Maximum screening-level percent crop treated (PCT) estimates were used for commodities for which data were available. If no PCT data were available, 100 PCT was assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance level residues and average estimates of PCT.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that paraquat does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and 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:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT in the chronic dietary risk assessment for existing uses as follows: Alfalfa, 1%; almonds, 25%; apples, 20%; apricots, 10%; artichokes, 25%; asparagus, 10%; avocados, 2.5%; barley, 1%; green beans, 1%; blackberries, 30%; blueberries, 10%; broccoli, 1%; cabbage, 2.5%; caneberries, 45%; cantaloupes, 5%; carrots, 2.5%; celery, 1%; cherries, 20%; corn, 2.5%; cotton, 15%; cucumbers, 5%; dry beans/peas, 2.5%; summer fallow, 1%; garlic, 1%; grapefruit, 2.5%; grapes, 20%; kiwifruit, 30%; lemons, 2.5%; lettuce, 1%;

nectarines, 10%; olives, 5%; onions, 5%; oranges, 5%; pasture, 1%; pastureland, 1%; peaches, 30%; peanuts, 20%; pears, 10%; green peas, 1%; pecans, 5%; peppers, 10%; pistachios, 25%; plums, 15%; potatoes, 5%; prunes, 10%; pumpkins, 5%; raspberries, 70%; rice, 1%; sorghum, 1%; soybeans, 1%; spinach, 5%; squash, 5%; strawberries, 10%; sugar beets, 1%; sugarcane, 5%; sunflowers, 1%; sweet corn, 2.5%; tangelos, 10%; tangerines, 10%; tobacco, 1%; tomatoes, 5%; walnuts, 15%; watermelons, 5%; wheat, 1%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable information on the regional consumption of food to which may be applied in a particular area.

2. *Dietary exposure from drinking water.* In the past the EPA has concluded that though paraquat undergoes minimal degradation in the environment, and thus is very persistent (as parent), paraquat residues are not expected in surface or ground water. Paraquat has a very high propensity to bind to solids, particularly clay, which makes it very immobile. In addition, paraquat 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). Because of its very low mobility and strong tendency to bind tightly to soils, paraquat 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. In most circumstances, the levels of paraquat 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.

In order to determine the most appropriate and realistic drinking water numbers to use in the human health risk assessment, the Agency reviewed a non-guideline supplemental mobility study that was conducted to evaluate the effects of traditional water treatment processes on paraquat and to determine the mobility of paraquat through soil filtration column. ^{14}C-paraquat, spiked at ~30 parts per billion (ppb) into the raw surface water samples from five representative U.S. community water supply facilities, was effectively removed by a combination of typical water treatment processes conducted on a laboratory-scale: The ''laboratory jar test'' (coagulation using alum with either lime or soda ash, flocculation and sedimentation), followed by duel media filtration (anthracite atop of filtering sand). The combination process was able to reduce the level of ^{14}C-paraquat to approximate or below the limit of detection of approximately 0.15 microgram/per liter (µg/L) ppb. The level of paraquat in the finished water of 0.15 ppb was used in both the acute and chronic assessments.

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 any specific use patterns that would result in residential exposure.

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

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

D. Safety Factor for Infants and Children

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

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

i. The toxicity database for paraquat is complete.

ii. There is no indication that paraquat is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that paraquat results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary exposure analysis is based on tolerance level residues and maximum estimates of PCT. The chronic analysis is based on tolerance level residues and average estimates of percent crop treated. For estimating levels of paraquat in drinking water, the Agency relied on a study that evaluated the effects of traditional water treatment processes on paraquat. These assessments will not underestimate the exposure and risks posed by paraquat.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to paraquat will occupy 21% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to paraquat from food and water will utilize 14% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for paraquat.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short- and intermediate-term adverse effect was identified; however, paraquat is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- and intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-term risk), no further assessment of short- and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for paraquat.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, 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 or to infants and children from aggregate exposure to paraquat residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate spectrophotometric method, Method I of the Pesticide Analytical Manual (PAM) Vol. II, is available for enforcing tolerances for residues of paraquat in/on plant commodities.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has established MRLs for paraquat in or on assorted tropical and subtropical fruits-inedible peel (includes all except atemoya, biriba, jaboticaba, starfruit, and wax jambu) at 0.01 ppm. These MRLs are different from the tolerances being established for paraquat in the United States. The Agency cannot harmonize with the Codex MRL because there were residues greater than 0.01 ppm in some of the data on which the proposed U.S tolerances are based.

V. Conclusion

Therefore, tolerances are established for residues of paraquat dichloride, (1,1′-dimethyl-4,4′-bipyridinium-ion) derived from application of either the bis(methylsulfate) or the dichloride salt (both calculated as the cation), in or on the following: Sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, lychee, longan, Spanish lime, rambutan, pulasan, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, feijoa, jaboticaba, wax jambu, starfruit (carambola), pawpaw, pomegranate, and white sapote at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885,

April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 27, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.205 is amended by alphabetically adding the following new entries to the table in paragraph (a) to read as follows:

§ 180.205 Paraquat; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Atemoya	0.05
* * * * *	
Biriba	0.05
* * * * *	
Canistel	0.05
* * * * *	
Cherimoya	0.05
* * * * *	
Custard apple	0.05
* * * * *	
Feijoa	0.05
* * * * *	
Ilama	0.05
Jaboticaba	0.05
* * * * *	
Longan	0.05
Lychee	0.05
Mango	0.05
* * * * *	
Pawpaw	0.05
* * * * *	
Pomegranate	0.05
* * * * *	
Pulasan	0.05
Rambutan	0.05
* * * * *	
Sapodilla	0.05
Sapote, black	0.05
Sapote, mamey	0.05
Sapote, white	0.05
* * * * *	
Soursop	0.05
* * * * *	
Spanish lime	0.05
* * * * *	
Star apple	0.05
Starfruit	0.05
* * * * *	
Sugar apple	0.05
* * * * *	
Wax jambu	0.05

* * * * *

[FR Doc. 2012–19320 Filed 8–8–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 2

[Docket No. USCG–2007–27668]

RIN 1625–AB35

Approval of Classification Societies

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: Federal law requires that classification societies conducting certain work in the United States be approved by the Coast Guard. In this rule, we finalize application procedures and performance standards that classification societies must meet in order to obtain approval by the Coast Guard. Through this final rule, we seek to improve marine safety and environmental protection by assuring the consistency and quality of work conducted by classification societies that review, examine, survey, or certify the construction, repair, or alteration of a vessel in the United States.

DATES: This final rule is effective September 10, 2012.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** on September 10, 2012.