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) (Public Law 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).

X. 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 174

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

Dated: May 7, 2010.

Steven Bradbury,

Acting Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

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

■ 2. Section 174.531 is added to subpart W to read as follows:

§174.531 Coat protein of plum pox virus; exemption from the requirement of a tolerance.

Residues of the coat protein of plum pox virus in or on the food commodities of fruit, stone, Group 12; and almond, are exempt from the requirement of a tolerance in these food commodities when expressed by the plant-incorporated protectant, coat protein gene of plum pox virus, and used in accordance with good agricultural practices.

[FR Doc. 2010–12579 Filed 5–25–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0920; FRL–8827–7]

Diquat Dibromide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of diquat, derived from applications of diquat dibromide, in or on canola meal and canola seed. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also corrects minor errors in the regulations for diquat at 40 CFR 180.266.

DATES: This regulation is effective May 26, 2010. Objections and requests for hearings must be received on or before July 26, 2010, 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–2009–0920. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

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–2009–0920 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 July 26, 2010. 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–2009–0920, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 4, 2010 (75 FR 5793) (FRL–8807–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7639) by Syngenta Crop Protection, Inc., P.O Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.226 be amended by establishing tolerances for residues of the herbicide diquat, 6,7-dihydrodipyrido(1,2-a:2'1'-c)pyrazinediium, derived from application of the dibromide salt and calculated as the cation, in or on canola, meal at 3.0 parts per million (ppm); and canola, seed at 1.0 ppm. That notice referenced a summary of the petition prepared by Sygenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the tolerance levels for canola, meal and canola, seed to 6.0 ppm and 2.0 ppm, respectively. The reason for these changes is explained in Unit IV.C.

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

Diquat dibromide exhibits low acute toxicity via the oral and inhalation routes of exposure but is moderately to severely toxic via the dermal route of exposure. Diquat dibromide is not a skin irritant nor a dermal sensitizer, but it is considered a moderate to severe eye irritant.

Subchronic and chronic studies in several species indicate multiple target sites for diquat dibromide toxicity. In subchronic dermal exposure studies in rats, diquat dibromide showed evidence of severe systemic toxicity, including high mortality and clinical signs. In a subchronic inhalation study in rats, the lung was determined to be the primary target site for inhalation toxicity. Chronic feeding studies in dogs, rats, mice, and rabbits indicate that target sites include the eyes and kidneys in both males and females and the adrenals and epididymides in males. There was no evidence of neurotoxicity in acute and subchronic studies in rats and no evidence of endocrine disruption or immunotoxicity in the toxicology studies available for diquat dibromide. In accordance with the 1986 Guidelines for Carcinogen Risk Assessment, diquat dibromide was classified in Group E (evidence of non-carcinogenicity to humans), based on a lack of evidence of carcinogenicity in acceptable studies in rats and mice and a lack of concern for mutagenicity.

There was no evidence of increased quantitative or qualitative susceptibility of *in utero* animals or of offspring in developmental toxicity studies in mice, rabbits, and rats or in the 2–generation reproduction study in rats. Effects in the offspring were observed only at or above dose levels which resulted in parental toxicity.

Specific information on the studies received and the nature of the adverse effects caused by diquat dibromide 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 document "*Diquat Dibromide: HED Risk Assessment for Tolerance Reassessment Eligibility Document (TRED.),*" p. 10 in docket ID number EPA–HQ–OPP–2010–0920.

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 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 diquat dibromide used for human risk assessment can be found at *http://www.regulations.gov* in the document "*Diquat Dibromide: Human Health Risk Assessment for the Section 18 Use on Canola in Oklahoma and Kentucky,*" p. 3 in docket ID number EPA–HQ–OPP–2010–0920.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to diquat dibromide, EPA considered exposure under the petitioned-for tolerances as well as all existing diquat dibromide tolerances in 40 CFR 180.226. EPA assessed dietary exposures from diquat dibromide 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 diquat dibromide. In the acute neurotoxicity study in rats, clinical signs of systemic toxicity (e.g., piloerection, diarrhea, urinary incontinence, upward curvature of the spine, subdued behavior) and decreased body-weight gains were observed after a single dose. 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, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all existing uses of diquat dibromide and the proposed new use on canola.

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 100 PCT for crops with direct diquat uses. For crops with tolerances to cover irrigation with diquat-treated water, anticipated residue levels from irrigation trials were used in conjunction with estimates of percent of crops irrigated. For fish, average residues were assumed. Default processing factors from Dietary Exposure Evaluation Model v.7.81 were used in the analysis for all processed commodities, except potato chips and dried potato flakes, which have their own tolerances based on submitted processing data.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified diquat dibromide in Group E (evidence of non-carcinogenicity to humans). Therefore, an exposure assessment to evaluate cancer risk is unnecessary for this chemical.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to section 408(f)(1) of FFDCA that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

EPA estimated PCT for several commodities that have tolerances to cover inadvertent residues of diquat from irrigation with diquat dibromide-treated water: Barley 36%; corn 19%; legume vegetables (subgroup 6C) 32%; oats 7%; sorghum 15%; soybean 9%; sugarcane 54%; and wheat 14%. One hundred PCT was assumed for all other irrigated crops and crops with direct diquat dibromide uses.

EPA estimated PCT for these commodities by estimating the percent crop irrigated, which serves as an upperbound for crops that may be exposed to diquat in irrigation water. The percent crop irrigated is an estimate of the share of total production that is irrigated, and is based on 2009 data from USDA's National Agricultural Statistics Service. Use of these estimates in the exposure assessment is conservative, because it is the equivalent of assuming 100% of irrigated crops are irrigated with water from diquat-treated canals. In fact, even in areas with surface water delivery systems, all irrigation canals may not be treated with diquat. Additionally, some crops, even in the heavily irrigated areas of the West, are not irrigated, such as dryland grain production.

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 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 diquat dibromide may be applied in a particular area.

2. *Dietary exposure from drinking water*. Diquat dibromide is registered for both terrestrial and aquatic uses. The Agency used screening level water exposure models to estimate residues of diquat in drinking water from the terrestrial uses. These simulation

models take into account data on the physical, chemical, and fate/transport characteristics of diquat dibromide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of diquat dibromide from terrestrial uses for acute exposures are estimated to be 13.2 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EDWCs for chronic exposures are estimated to be 0.4 ppb for surface water and 0.006 ppb for ground water.

Diquat dibromide is registered for aquatic weed control and, as such, may be applied directly to bodies of water. The maximum contaminant level (MCL) for diquat established by the EPA Office of Water is 20 ppb. EPA does not expect residues from direct applications of diquat dibromide to water to exceed the MCL because of the tendency of diquat to sorb nearly irreversably to soil and sediment.

Since direct aquatic applications are estimated to result in higher concentrations of diquat in drinking water than terrestrial uses, EPA used the MCL of 20 ppb to assess the contribution to drinking water in both the acute and chronic dietary risk 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).

Diquat dibromide is currently registered for the following uses that could result in residential exposures: Applications to turf, recreational ponds and lakes; general weed control in and around home and garden sites; and landscape uses by residential handlers. EPA assessed residential exposure using the following assumptions: Residential handlers may receive short-term dermal and inhalation exposure when applying diquat dibromide products. EPA assessed short-term dermal and inhalation residential handler exposures for four scenarios: Mixing, loading, and applying products with a low-pressure handwand or backpack sprayer; and applying diquat dibromide products in an aerosol can or using a trigger pump sprayer. Adults and children may also be exposed to diquat dibromide residues on a short-term basis through dermal contact with treated turf and from swimming activities in treated recreational ponds and lakes. In addition, toddlers may receive short-term oral exposure from incidental ingestion during post-application activities on treated turf. EPA assessed the following post-application exposure scenarios:

i. Adult and toddler post-application dermal exposure,

ii. Recreational exposure from playing golf on treated turf,

iii. Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer,

iv. Toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass,

v. Toddlers' incidental ingestion of soil from pesticide-treated residential areas, and

vi. Recreational exposure of adults and children from swimming in treated ponds and lakes.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 diquat dibromide to share a common mechanism of toxicity with any other substances, and diquat dibromide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that diquat dibromide 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 website 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 Food Quality Protection Act (FQPA) Safety Factor (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*. The prenatal and postnatal toxicity database for diquat dibromide includes developmental toxicity studies in rats, mice, and rabbits and a 2–generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring in any of these studies.

In the developmental study in rats, fetal effects (decreased fetal, litter, and gravid uterine weights; an increased incidence of fetuses with hemorrhagic kidney; and delayed skeletal ossification) occurred at a higher dose than the dose causing effects in maternal animals (decreased body-weight gains and food consumption during dosing). At the LOAEL for fetal effects, maternal effects included one death and clinical signs (piloerection and subdued activity). In the developmental study in rabbits, fetal effects (decreased fetal body weight, an increased incidence of friable/mottled livers, and an increased incidence of minor skeletal alterations) also occurred at a higher dose than the dose causing maternal toxicity (body-weight loss and decreased food consumption). At the LOAEL for fetal effects, maternal effects included deaths and clinical signs (diarrhea, subdued activity, thin appearance, mucus, blood, little or no feces in tray). Results in the mouse developmental toxicity study were similar. Fetal effects (decreased fetal body weight and an increased incidence of overall skeletal alterations) occurred at a higher dose than the dose causing maternal toxicity (mortality, clinical signs (piloerection, respiratory sounds), and decreased body weight gain during the dosing period). Maternal effects at the LOAEL for fetal effects included additional clinical signs (abnormal posture, lethargy, tremors, unsteadiness on feet, emaciation, ptosis) and a slight decrease in body weight (91% of control) at termination.

In the 2–generation reproduction study in rats, offspring effects included a decreased number of live pups per litter on days 1–22, decreased pup body weight gain during lactation, and an increased incidence of kidney lesions. Parental effects, including clinical signs, ulceration of the tongue, and partial/

total cataract, were observed at the same dose causing toxicity in the offspring.

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 diquat dibromide is adequate to assess its prenatal and postnatal toxicity. In accordance with Part 158 Toxicology Data requirements, an immunotoxicity study (Harmonized Test Guideline 870.7800) is required for diquat dibromide. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for evidence of immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by diquat dibromide. Therefore, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for diquat dibromide, and an additional database uncertainty factor is not needed to account for the lack of this study.

ii. There is no indication that diquat dibromide 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 diquat dibromide results in increased susceptibility in *in utero* rats, rabbits, or mice in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no significant residual uncertainties identified in the exposure databases for diquat dibromide. Additional information from the canola residue studies on the length of storage of canola samples prior to analysis and confirmatory residue data for canola are required. However, as explained in this Unit, EPA does not expect these data to have a measurable impact on exposure estimates for diquat dibromide.

a. Data from the West German and United Kingdom field trials on the length of storage of canola samples prior to analysis were not submitted. EPA is requiring these data; however, EPA already has data for other crops showing that diquat dibromide is stable in frozen storage for 6 to 8 months. In addition, based on its structure, EPA expects diquat dibromide to be stable in frozen storage much longer than the 6 to 8 months for which data are available. Therefore, EPA does not expect the length of time the samples were stored to affect its conclusions regarding the field trial studies.

b. EPA has determined that the residue trials conducted in European Union (EU) countries are adequate to support tolerances and conditional registration of diquat dibromide as a preharvest desiccant on canola in the United States. However, EPA is aware that the Interregional Research Project number 4 (IR-4) has conducted field trials in the U.S. that would support this same use pattern. Residues of diquat dibromide on canola grown in the U.S. are not expected to differ significantly from residues reported in the EU studies, since harvest aid/desiccant applications are made late in the growing season with little time between application and harvest. In addition, since the recommended tolerances for canola seed and meal have been increased by a factor of 2X to harmonize with Codex (See Unit IV.C below), there is little chance residues in the U.S. trials will exceed these tolerances. Nevertheless, since the IR-4 field work has already been completed and the study reports will be available in July, 2011, EPA is requiring that these studies be submitted as a condition of registration to confirm the tolerance levels. EPA notes that canola is a minor contributor to estimated dietary exposure in both the acute and chronic dietary exposure assessments, accounting for less than 1% of total exposure for the most highly exposed population subgroup (children 1 to 2 years old) in each case. Therefore, even if the U.S. field trials were to indicate higher residues than the EU trials, the impact on dietary exposure would be negligible.

The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. The chronic dietary exposure assessment was refined using reliable irrigation data from USDA, average residues for fish from valid residue studies, and anticipated residues for irrigated crops that were derived from valid irrigation trials. The established MCL of 20 ppb used in the acute and chronic dietary exposure assessments is a conservative value that is considered protective of exposures from both terrestrial and direct aquatic applications of diquat dibromide. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by diquat dibromide.

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 aPAD and chronic 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 diquat dibromide will occupy 1% of the aPAD for children, 1 to 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 diquat dibromide from food and water will utilize 35% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of diquat dibromide is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Diquat dibromide is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to diquat dibromide.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 110 for infants and toddlers, 150 for children 6 to 12 years old, and 260 for teenagers and adults. The aggregate MOEs for infants and toddlers include dietary exposures from food and drinking water as well as dermal and incidental oral postapplication exposures from activities on treated turf. The aggregate MOE for children includes dietary exposures from food and drinking water as well as dermal postapplication exposure from activities on treated turf and exposures from swimming in ponds and lakes treated with diquat dibromide. The aggregate MOEs for teenagers and adult population subgroups include dietary exposures, residential handler dermal exposures, dermal postapplication

exposures from activities on treated turf, and exposures from swimming in ponds and lakes treated with diquat dibromide. EPA did not aggregate residential handler inhalation exposures with exposures by other routes in the aggregate exposure assessment for teenagers and adults, since the effects associated with inhalation exposure (increased mean lung weight in males, mottling and reddening of lungs in females, and lung lesions) are different from those used to assess the dermal and oral routes (body-weight loss and decreased food consumption). Inhalation MOEs for residential handlers ranged from 570 (aerosol can application) to 11,000,000 (trigger sprayer). Because EPA's level of concern for diquat dibromide is a MOE of 100 or below, these MOEs are not of concern.

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

EPA did not establish a POD for use in assessing intermediate-term residential exposures, because diquat dibromide is not registered for any use patterns that would result in such exposures. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for diquat dibromide.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, diquat dibromide is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatographic Method (HPLC)) 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*. Method A (a spectrophotometric method) in the Pesticide Analytical Manual (PAM) Vol. II. is also available to enforce tolerances for residues of diquat in/on plant and livestock commodities.

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 section 408(b)(4) of FFDCA. The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for diquat in or on rapeseed (which includes canola seed) at 2.0 ppm. This MRL is the same as the tolerance being established for diquat dibromide on canola, seed in the United States.

C. Revisions to Petitioned-For Tolerances

EPA has increased the tolerance level for canola, seed from 1.0 ppm to 2.0 ppm to harmonize with the established Codex MRL of 2.0 ppm for rapeseed. EPA has also increased the tolerance level for canola meal from 3.0 ppm to 6.0 ppm. The tolerance level for meal was derived by applying the maximum theoretical concentration factor of 3X for canola meal to the canola seed tolerance of 2.0 ppm.

EPA is also correcting minor errors in the regulations for diquat at 40 CFR 180.226, as follows: EPA is correcting typographical errors in the chemical name for diquat in paragraphs (a)(2)(i) and (a)(3). EPA is also removing paragraph (a)(4), which reads "There are no U.S. registrations as of December 6, 1995." This statement was originally included as a footnote to import tolerances for banana and coffee, established in the **Federal Register** of March 27, 1996 (61 FR 13474) (FRL–5348–1). The statement was inadvertently moved to a separate paragraph in subsequent editions of the CFR. EPA is correcting this error by removing paragraph (a)(4) and adding an updated statement regarding U.S. registrations as a footnote to the banana and coffee tolerances. The updated footnote to the table in paragraph (a)(3) reads "There are no U.S. registrations as of May 26, 2010."

V. Conclusion

Therefore, tolerances are established for residues of diquat, 6,7-dihydrodipyrido(1,2-a:2'1'-c)pyrazinediium derived from application of the dibromide salt and calculated as the cation, in or on canola, meal at 6.0 ppm; and canola, seed at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such,

the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 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: May 18, 2010.

Daniel J. Rosenblatt,

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 180.226 is amended as follows:

i. Alphabetically add commodities to the table in paragraph (a)(1);

ii. Revise introductory text in paragraph (a)(2)(i);

iii. Revise paragraph (a)(3);

iv. Remove paragraph (a)(4); and

v. Redesignate paragraph (a)(5) as (a)(4).

The amendments read as follows:

§ 180.226 Diquat; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
* * *	* *
Canola, meal	6.0
Canola, seed	2.0
* * *	* *

(2)(i) Tolerances are established for residues of the herbicide diquat (6,7 dihydrodipyrido(1,2-a:2'1'-c)pyrazinediium) (calculated as the cation) derived from the application of the dibromide salt to ponds, lakes, reservoirs, marshes, drainage ditches, canals, streams, and rivers which are slow-moving or quiescent in programs of the Corp of Engineers or other Federal or State public agencies and to ponds, lakes and drainage ditches only where there is little or no outflow of water and which are totally under the control of the user, in or on the following food commodities:

* * * * *

(3) Tolerances are established for the plant growth regulator diquat (6,7 dihydrodipyrido(1,2-a:2'1'-c)pyrazinediium) derived from application of the dibromide salt and calculated as the cation in or on the following food commodites:

Commodity	Parts per million
Banana[1]	0.05
Coffee, bean, green[1]	0.05
Soybean, hulls	0.6

[1]There are no U.S. registrations as of May 26, 2010.

* * * * *

[FR Doc. 2010–12648 Filed 5–25–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0273; FRL–8825–3]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on multiple commodities which are identified and discussed later in this document. This regulation additionally revises several established tolerances for residues of novaluron. Makhteshim-Agan of North America, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 26, 2010. Objections and requests for hearings must be received on or before July 26, 2010, 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–2009–0273. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@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).