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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0232; FRL-9929-57]

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 and removes several existing tolerances which are identified and discussed later in this document. This regulation additionally revises existing tolerances in or on vegetable, cucurbit, group 9; and plum, prune, dried. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2014-0232, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., 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: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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.ecfr.gov/cgi-bin/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-2014-0232 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0232, 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 CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (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.html*. 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 December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8241) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W., Princeton, NJ, 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide novaluron, (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2- (trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide), in or on avocado at 0.60 parts per million (ppm); carrot at 0.05 ppm; bean at 0.60 ppm; vegetable, fruiting, group 8–10 at 1.0 ppm; fruit, pome, group 11–10 at 2.0 ppm; cherry subgroup 12–12A at 8.0 ppm; peach subgroup 12–12B at 1.9 ppm; and plum subgroup 12–12C at 1.9 ppm.

Upon approval of the petitioned-for tolerances listed above, the petition proposed to remove the following established tolerances for residues of novaluron from 40 CFR 180.598: Bean, succulent, snap at 0.60 ppm; bean, dry, seed at 0.30 ppm; cherry at 8.0 ppm; fruit, pome, group 11 at 2.0 ppm; fruit, stone, group 12, except cherry at 1.9 ppm; vegetable, fruiting, group 8 at 1.0 ppm; cocona at 1.0 ppm; African eggplant at 1.0 ppm; pea eggplant at 1.0 ppm; scarlet eggplant at 1.0 ppm; goji berry at 1.0 ppm; garden huckleberry at 1.0 ppm; martynia at 1.0 ppm; naranjilla at 1.0 ppm; okra at 1.0 ppm; roselle at 1.0 ppm; sunberry at 1.0 ppm; bush tomato at 1.0 ppm; currant tomato at 1.0 ppm; and tree tomato at 1.0 ppm. These tolerances were requested for removal because they will be superseded by establishment of the petitioned-for tolerances. That document referenced a summary of the petition prepared on behalf of IR-4 by Makhteshim-Agan of North America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised several proposed tolerances. EPA has also determined that the previously established tolerances in or on vegetable, cucurbit, group 9 and plum, prune, dried should be revised. Finally, EPA determined that establishing a tolerance on bean is not appropriate; rather, a tolerance should be established on bean, succulent and the previously established tolerance on bean, dry, seed should not be removed. The reasons for these changes are explained in Unit IV.D.

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 novaluron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with novaluron 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.

In subchronic and chronic toxicity studies, novaluron primarily produced hematotoxic effects such as methemoglobinemia, decreased hemoglobin, decreased hematocrit, decreased red blood cells (RBCs) (or erythrocytes) and increased reticulocyte counts that were associated with compensatory erythropoiesis. Increased spleen weights or hemosiderosis in the spleen were considered to be due to enhanced removal of damaged erythrocytes and not to a direct immunotoxic effect.

There was no maternal or developmental toxicity seen in the rat and rabbit developmental toxicity studies up to the limit doses. In the 2-generation reproductive toxicity study in rats, both parental and offspring toxicity (increased spleen weights) were observed at the same dose. Reproductive toxicity, including decreases in epididymal sperm counts and increased age at preputial separation in the F1 generation, was observed at a higher dose than the increased spleen weights and were consistent with the primary effects in the database.

Clinical signs of neurotoxicity (piloerection, irregular breathing), changes in functional observational battery (FOB) parameters (increased head swaying, abnormal gait), and neuropathology (sciatic and tibial nerve degeneration) were seen in the rat acute neurotoxicity study at the limit dose. However, no signs of neurotoxicity or neuropathology were observed in the subchronic neurotoxicity study in rats at similar doses or in any other subchronic or chronic toxicity study in rats, mice, or dogs. In the submitted immunotoxicity study, the only sign of potential immunotoxicity for novaluron was a decreased anti-sheep red blood cell (anti-SRBC) response at twice the limit dose in female rats. There was no evidence of carcinogenic potential

in either the rat or mouse carcinogenicity studies, and there was also no concern for genotoxicity or mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by novaluron 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: "Novaluron: Human Health Risk Assessment for the Petition for the Establishment of Permanent Tolerances for Residues of Novaluron in/on Avocado; Carrot; Succulent Bean; Vegetable, Fruiting, Crop Group 8-10; Fruit, Pome, Crop Group 11-10; Cherry Subgroup 12-12A; Peach Subgroup 12-12B; and Plum Subgroup 12-12C; and Revisions to the Label to Include Uses on Greenhouse-Grown Cucumber" at pages 36-40 in docket ID number EPA-HQ-OPP-2014-0232.

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 novaluron used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Novaluron for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population, including infants and children)	An endpoint of concern attributable to a single dose was not identified, and an acute RfD was not established.		
Chronic dietary (All populations)	NOAEL= 1.1 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	Chronic RfD = 0.011 mg/kg/day cPAD = 0.011 mg/kg/day	Combined chronic toxicity/carcinogenicity feeding in rat LOAEL = 30.6 mg/kg/day based on erythrocyte damage resulting in a compensatory regenerative anemia.
Incidental oral, all durations	NOAEL= 4.38 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day feeding study in rat LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit, and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver).
Inhalation, all	Inhalation (or oral) study NOAEL= 4.38	LOC for MOE	90-day feeding study in rat

durations	mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	= 100	LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit, and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver).
Cancer (Oral, dermal, inhalation)	Classified as not likely to be carcinogenic to humans.		

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 novaluron, EPA considered exposure under the petitioned-for tolerances as well as all existing novaluron tolerances in 40 CFR 180.598. EPA assessed dietary exposures from novaluron 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. No such effects were identified in the toxicological studies for novaluron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA under the National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA); 2003-2008. As to residue levels in food, EPA incorporated average field trial residues for the majority of commodities; anticipated residues

(ARs) for meat, milk, hog, and poultry commodities; and average percent crop treated (PCT) data for apples, blueberries, cabbage, cauliflower, cotton, dry beans, pears, peppers, potatoes, strawberries, and tomatoes. Percent crop treated for new use (PCTn) data were incorporated for the recently registered grain sorghum and sweet corn uses. For the remaining food commodities, 100 PCT was assumed. The registered food-handling use was also incorporated into the dietary assessment. Empirical processing factors were utilized for apple juice (translated to pear and stone fruit juice), cottonseed oil, dried plums, and tomato paste and purée. Dietary Exposure Evaluation Model (DEEM) (ver. 7.81) default processing factors were used for the remaining processed commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that novaluron 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)(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 FFDCA section 408(f)(1) 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses as follows:

Apple, 10%; blueberry, 1%; cabbage, 5%; cauliflower, 2.5%; cotton, 2.5%; dry beans, 1%; pear, 15%; pepper, 2.5%; potato, 2.5%; strawberry, 35%; and tomato, 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 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 estimated the PCT for new uses as follows: Grain sorghum, 2%; and sweet corn, 36%.

EPA estimates PCTn for novaluron based on the PCT of the dominant pesticide (i.e., the one with the greatest PCT) on that site over the three most recent years of available data. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant insecticide on the use site is selected for comparison with a new insecticide). The PCTs included in the analysis may be for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PCTn, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factors that bear on whether the estimated PCTn could be exceeded are: the extent of pest pressure on the crops in question; the pest spectrum of the new pesticide in comparison with the market leaders as well as whether the market leaders are well-established for this use; and resistance concerns with the market leaders.

Novaluron specifically targets lepidopterous insects, which are not key pests of sorghum but are key pests of sweet com. However, novaluron has a relatively narrow spectrum of pest activity when compared to the market leader insecticides. In addition, there are no resistance or pest pressure issues as indicated in Section 18 Emergency Exemption requests for use of novaluron on sorghum or sweet com. All information currently available has been considered

for novaluron use on sorghum and sweet com, and it is the opinion of EPA that it is unlikely that actual PCT for novaluron will exceed the estimated PCT for new uses during the next five years.

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 novaluron may be applied in a particular area.

2. *Dietary exposure from drinking water*. The residues of concern in drinking water for risk assessment purposes are novaluron, the chlorophenyl urea degradate, and the chloroaniline degradates. The estimated drinking water concentrations (EDWCs) for each of these was calculated using a molecular weight conversion and then combined for each modeled scenario. The degradates are assumed to have equal toxicity to the parent. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for novaluron and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of novaluron and its degradates. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), the Screening Concentration in Ground Water (SCI-GROW), and Pesticide Root Zone Model Ground Water (PRZM GW) models, the combined EDWCs of novaluron, chlorophenyl urea, and chloroaniline for chronic exposures are estimated to be 16.7 ppb for surface water and 77.8 ppb for groundwater.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 77.8 ppb was used to assess the contribution to drinking water.

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

Novaluron is currently registered for the following uses that could result in residential exposures: Indoor and outdoor crack and crevice or perimeter applications in residential areas and their immediate surroundings, including homes and apartment buildings; on modes of transportation; and as a spot-on use for pets. EPA assessed residential exposure using the following assumptions:

Adult handlers were assessed for potential short-term inhalation exposures from mixing, loading, and applying novaluron via manually-pressurized hand wand and from liquid applications of novaluron to turf. Adults were also assessed for potential short-term post-application inhalation exposures to novaluron from indoor uses. For children 1 to <2 years old, short-term post-application inhalation and incidental oral exposures were assessed resulting from hand-to-mouth contact with treated residential areas, turf, and from contact with treated

pets. There is also the potential for intermediate-term and long-term post-application hand-to-mouth exposures to children 1 to <2 years old from the registered pet spot-on use of novaluron. Inhalation exposures are considered negligible for this exposure scenario; therefore, the intermediate- and long-term aggregate risk estimates do not include inhalation exposures. For adults, inhalation exposure is expected to be negligible for intermediate- and long-term durations and was not included in the aggregate assessment. Additionally, a dermal endpoint has not been selected for novaluron, so dermal exposures to adults or children were not assessed.

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 novaluron to share a common mechanism of toxicity with any other substances, and novaluron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that novaluron 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 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 toxicology database for novaluron includes rat and rabbit prenatal developmental toxicity studies and a two-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility following *in utero* exposure to rats or rabbits in the developmental toxicity studies and no evidence of increased quantitative or qualitative susceptibility of offspring in the reproduction study. Neither maternal nor developmental toxicity was seen in the developmental studies up to the limit doses (1,000 mg/kg/day). In the 2-generation reproductive study in rats, offspring and parental toxicity (increased absolute and relative spleen weights) were similar and occurred at the same dose (74.2 mg/kg/day). Additionally, reproductive effects (decreases in epididymal sperm counts and increased age at preputial separation in the F1 generation) occurred at a higher dose than that which resulted in parental toxicity.

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 novaluron is complete.

ii. Acute and subchronic rat neurotoxicity studies were performed for novaluron. The clinical signs of neurotoxicity, changes in FOB parameters, and neuropathology were seen in the acute neurotoxicity study at the limit dose (2,000 mg/kg/day) only and were not reproduced at similar, repeated doses in the subchronic neurotoxicity study. In addition, no evidence of neuropathology was observed in subchronic and chronic toxicity studies in rats, mice, or dogs. Therefore, novaluron is not considered 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 novaluron 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 chronic dietary food exposure assessment was performed using average field trial residues, anticipated residues for livestock commodities, average PCT and PCTn data for some commodities, and empirical and default processing factors. For the remaining food commodities, 100 PCT was assumed. The registered food handling use was also incorporated into the dietary assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to novaluron in drinking water. 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 novaluron.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, novaluron is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to novaluron from food and water will utilize 73% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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). Novaluron 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 novaluron.

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 1,560 for adults and 350 for children 1 to <2 years old. Because EPA's level of concern for novaluron is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate- and long-term risk*. Intermediate- and long-term aggregate exposure takes into account intermediate- and long-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). **N**ovaluron is currently registered for uses that could result in intermediate- and long-term residential exposure, and

the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate- and long-term residential exposures to novaluron.

Using the exposure assumptions described in this unit for intermediate- and long-term exposures, EPA has concluded that the combined intermediate- and long-term food, water, and residential exposures result in an aggregate MOE of 530 for children 1 to <2 years old. For adults, since there is no dermal endpoint and inhalation exposure is expected to be negligible, the average dietary consumption (food and drinking water) exposure estimate is representative of intermediate- and long-term aggregate risk, and results in an MOE of 1640. Because EPA's level of concern for novaluron is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, novaluron 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 novaluron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies, gas chromatography/electron-capture detection (GC/ECD) and high-performance liquid chromatography/ultraviolet (HPLC/UV), are available to enforce the tolerance expression.

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 novaluron in or on common beans (pods and/or immature seeds) at 0.7 ppm; pome fruit at 3 ppm; cucurbit vegetables at 0.2 ppm; and prunes at 3.0 ppm. EPA is establishing tolerances in or on succulent bean at 0.70 ppm; pome fruit crop group 11-10 at 3.0 ppm; cucurbit vegetable crop group 9 at 0.20 ppm; and dried prune at 3.0 ppm in order to harmonize with Codex. The Codex has additionally established a tolerance in or on fruiting vegetables other than cucurbits at 0.7 ppm and stone fruits at 7 ppm. Because EPA is recommending a tolerance in or on fruiting vegetables crop group 8-10 (1.0 ppm) that is higher than Codex, EPA cannot harmonize this tolerance. Residue data for greenhouse tomatoes supports the 1.0 ppm tolerance for the group 8-10 tolerance.

The data supporting the EPA petition result in stone fruit tolerances that are either higher (cherry subgroup 12-12A at 8.0 ppm) or much lower (peach subgroup 12-12B and plum subgroup 12-12C at 1.9 ppm) than the established Codex MRL for stone fruit at 7 ppm. EPA notes that the stone fruit tolerances are not harmonized with associated Codex MRLs on these commodities because it has been determined that the major export market for these

commodities is Canada. Therefore, in order to maintain harmonization of U.S. tolerances and Canadian MRLs for these commodities, the EPA is establishing these subgroup tolerances at the levels that align with the Canadian MRLs. No Codex MRLs have been established for residues of novaluron in or on avocado or carrot.

C. Response to Comments

One comment was received to the batched Notice of Filing that provided brief and general concerns about toxins and potential impacts to bees, but the commenter did not cite a specific petition within the Notice. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), 69 FR 63096-63098 (October 29, 2004) for the Agency's response to these objections.

D. Revisions to Petitioned-For Tolerances

The Agency was petitioned to establish a tolerance of novaluron in or on plum subgroup 12-12C. As a part of that request, the Agency reviewed the existing tolerance on dried prune, and determined that the tolerance should be amended from 2.6 ppm to 3.0 ppm in order to harmonize with Codex. Data were also submitted and reviewed by EPA to allow the use of novaluron in or on greenhouse-grown cucumbers. During review, the Agency determined that the existing tolerance in or on cucurbit vegetable group 9 (which includes cucumber) should be amended from 0.15 ppm to 0.20 ppm in order to harmonize with Codex.

EPA was also petitioned to establish a tolerance in or on bean at 0.60 ppm and to remove the existing tolerance in or on dry bean seed at 0.30 ppm upon approval of the proposed bean tolerance. However, the Agency determined that separate tolerances should be established in or on succulent bean and dry bean seed. Therefore, this action will not remove the existing tolerance for the use of novaluron in or on dry bean seed at 0.30 ppm, and the

Agency determined that a tolerance in or on succulent bean at 0.70 ppm is appropriate in order to harmonize with the established Codex tolerance on beans. Finally, EPA revised the proposed pome fruit crop group 11-10 tolerance from 2.0 ppm to 3.0 ppm in order to harmonize with the established Codex MRL.

V. Conclusion

Therefore, tolerances are established for residues of novaluron, (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2- (trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide), in or on avocado at 0.60 ppm; bean, succulent at 0.70 ppm; carrot at 0.05 ppm; cherry subgroup 12-12A at 8.0 ppm; fruit, pome, group 11-10 at 3.0 ppm; peach subgroup 12-12B at 1.9 ppm; plum subgroup 12-12C at 1.9 ppm; and vegetable, fruiting, group 8-10 at 1.0 ppm. This regulation additionally revises the existing tolerances in or on vegetable, cucurbit, group 9 from 0.15 ppm to 0.20 ppm; and plum, prune, dried from 2.6 ppm to 3.0 ppm. Finally, this regulation removes established tolerances in or on bean, snap, succulent; cherry; cocona; fruit, pome, group 11; fruit, stone, group 12, except cherry; eggplant, African; eggplant, pea; eggplant, scarlet; goji berry; huckleberry, garden; martynia; naranjilla; okra; roselle; sunberry; tomato, bush; tomato, currant; tomato, tree; and vegetable, fruiting, group 8.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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 9, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.598:

a. Remove the entries in the table in paragraph (a) for " Bean, snap, succulent", "Cherry", "Cocona", "Eggplant, African", "Eggplant, pea", "Eggplant, scarlet", "Fruit, pome, group 11", "Fruit, stone, group 12, except cherry", "Goji berry", "Huckleberry, garden", "Martynia", "Naranjilla", "Okra", "Roselle;" "Sunberry", "Tomato, bush", "Tomato, currant", "Tomato, tree", and "Vegetable, fruiting, group 8".

b. Add alphabetically the entries for "Avocado", "Bean, succulent", "Carrot", "Cherry subgroup 12-12A", "Fruit, pome, group 11-10", "Peach subgroup 12-12B", "Plum subgroup 12-12-C", and "Vegetable, fruiting, group 8-10" to the table in paragraph (a).

c. Revise the entries for "Plum, prune, dried", and "Vegetable, cucurbit, group 9" in the table in paragraph (a).

The additions and revisions read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Avocado	0.60
* * * * * * *	
Bean, succulent	0.70
* * * * * * *	
Carrot	0.05
* * * * * * *	
Cherry subgroup 12-12A	8.0

* * * * * * *	
Fruit, pome, group 11-10	3.0
* * * * * * *	
Peach subgroup 12-12B	1.9
* * * * * * *	
Plum, prune, dried	3.0
Plum subgroup 12-12C	1.9
* * * * * * *	
Vegetable, cucurbit, group 9	0.20
Vegetable, fruiting, group 8-10	1.0
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[FR Doc. 2015-17676 Filed: 7/21/2015 08:45 am; Publication Date: 7/22/2015]