as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: June 21, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.480 revise paragraph (a) introductory text and revise the entry ''Pepper'' in the table in paragraph (a) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) Tolerances are established for residues of the fungicide fenbuconazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of fenbuconazole, alpha-[2-(4-chlorophenyl)-ethyl]-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile, and its metabolites RH-9129, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3 H-furanone, and RH-9130, trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3 H-furanone, calculated as the stoichiometric equivalent of fenbuconazole, in or on the following agricultural commodities.

Commodity	Parts per million
* * * * *	
Pepper	1.0
* * * * *	

* * * * *

[FR Doc. 2013–15867 Filed 7–2–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0291; FRL–9389–7]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on peanut and soybean, seed. Makhteshim-Agan of North America requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation additionally deletes the time-limited tolerance for strawberry, as that tolerance expired on December 31, 2011.

DATES: This regulation is effective July 3, 2013. Objections and requests for hearings must be received on or before September 3, 2013, 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–2012–0291, 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), EPA West 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: Jennifer Gaines, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5967; email address: *gaines.jennifer@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–2012–0291 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 September 3, 2013. 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–2012–0291, 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.htm.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL–9353–6), 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 2F7999) by Makhteshim-Agan of North America, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR 180.598 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 peanuts at 0.01 parts per million (ppm) and soybean, seed at 0.06 ppm. That document referenced a summary of the petition prepared by Makhteshim-Agan of North America, 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 revised the tolerance level for soybean, seed. The reason for this change 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 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.

Novaluron has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant and is not a dermal sensitizer. In subchronic and chronic toxicity studies, novaluron primarily produced hematotoxic effects such as methemoglobinemia, decreased hemoglobin, decreased hematocrit, and decreased red blood cells (RBCs) (or erythrocytes) associated with increased erythropoiesis. Increased spleen weights and/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 (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.

Signs of neurotoxicity (piloerection, irregular breathing), changes in functional observational batter 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. Therefore, there is no concern for neurotoxicity resulting from exposure to novaluron.

There was no evidence of carcinogenic potential in either the rat or mouse carcinogenicity studies. There was no concern for genotoxicity or mutagenicity. Therefore novaluron was classified as ''not likely to be carcinogenic to humans.''

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 Proposed Section 3 Uses on Peanut and Soybean at pp. 37–40 in docket ID number EPA–HQ–OPP–2012–0291.

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 the NOAEL and the LOAEL are indentified. 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).	None	None	An endpoint of concern attributable to a single dose was not identified. An acute RfD was not established.
Chronic dietary (All populations)	NOAEL = 1.1 mg/kg/day. UF_A = 10X UF_H = 10X 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 short-term (1 to 30 days) and Intermediate-Term (1 to 6 months).	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).
Dermal short-term (1 to 30 days)	Not applicable and none.	None	No toxicity was observed at the limit dose in the dermal study and there were no developmental toxicity concerns at the limit-dose; therefore, quantification of short-term dermal risk is not necessary.
Dermal intermediate-term (1 to 6 months).	Dermal (or oral) study NOAEL = 4.38 mg/kg/day (dermal absorption rate = 10% when appropriate). 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 short-term (1 to 30 days) and Intermediate Term (1 to 6 months).	Inhalation (or oral) study NOAEL = 4.38 mg/kg/day (inhalation absorption rate = 100%). 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).
Cancer (Oral, dermal, inhalation)	Classification: 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 percent crop treated (PCT) data for apples, cabbage, cauliflower, cotton, pears, potatoes, strawberries, and tomatoes and utilized estimates for PCT for recently registered uses for grain sorghum and sweet corn. 100 PCT was assumed for the remaining food commodities. Anticipated residues (ARs) for meat, milk, hog, and poultry commodities were calculated based on the proposed/registered uses, and incorporated average field trial residues, percent crop treated for new uses (PCTn) data for grain sorghum and sweet corn, average PCT data for apple and cotton, and an assumption of 100 PCT for sugarcane, aspirated grain fractions (AGF), and cowpea seed.

The chronic analysis also incorporated average field trial residues, tolerance-level residues for the proposed commodities, average greenhouse trial residue for tomatoes, and half-limit of quantitation (LOQ) residues for food commodities other than those covered by a higher tolerance

as a result of use on growing crops from the registered use in food and feed handling establishments. Additionally, empirical processing factors for apple juice (translated to pear and stone fruit juice), cottonseed oil, dried plums, and tomato paste and purée, and Dietary Exposure Evaluation Model (DEEM) (ver. 7.81) default processing factors for the remaining processed commodities, where provided were incorporated.

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 percent crop treated (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 PCT for existing uses as follows: Apples at 10%; cabbage at 10%; cauliflower at < 2.5%, cotton at < 2.5%, pears at 15%, potatoes at < 2.5%, strawberries at 35%, and tomatoes at < 1%.

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 6–7 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 recently approved uses as follows: Sweet corn at 36% and grain sorghum at 2%.

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 doesn 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.

The estimated PCT for new uses, 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 PCT for new uses could be exceeded are:

1. The extent of pest pressure on the crops in question;

2. 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

3. Resistance concerns with the market leaders. Novaluron specifically targets lepidopterous insects, which are not key pests of sorghum but are key pests of sweet corn. However, novaluron has a relatively narrow spectrum of pest activity when compared to the market leader insecticides.

All information currently available has been considered for novaluron use on sorghum and sweet corn, and it is the opinion of the Agency that it is unlikely that actual PCT for novaluron will exceed the estimated PCT for new uses during the next 5 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 are novaluron and it chlorophenyl urea and chloroaniline degradates. 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. 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.*

EPA utilized the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) for estimating

parent novaluron in surface water, the Tier 1 FQPA Index Reservoir Screening Tool (FIRST) model for surface water estimates for chlorophenyl urea and chloroaniline degradates, and the Screening Concentration in Ground Water (SCI–GROW) model for novaluron, chorophenyl urea, and chloroaniline in ground water. Based on these models, the estimated drinking water concentrations (EDWCs) of novaluron, chlorophenyl urea, and chloroaniline for chronic exposures for non-cancer assessments are estimated to be 0.41 parts per billion (ppb), 0.375 ppb, and 3.301 ppb respectively, for surface water and 0.00137 ppb, 0.00149 ppb, and 0.00658 ppb respectively for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The highest 1-in-10 year annual mean surface water EDWCs were combined to estimate drinking water exposures. For chronic dietary risk assessment, the water concentration of value 4.086 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 uses for the control of crickets (cracks and crevice and spot treatments) in residential areas such as homes and apartment buildings, and their immediate surroundings, and on modes of transportation. There is a potential for exposure in residential settings during the application process for homeowners who use products containing novaluron.

Additionally, exposure routes were assessed for post-application exposures for adults and children via inhalation routes and post-application incidental oral (hand-to-mouth) exposure for children (1 to < 2 years old). Additionally, a combined residential assessment that consisted of children (1 to < 2 years old) inhalation and oral (hand-to-mouth) post-application exposure was included. Details of the residential risk exposure and risk assessment are contained in the EPA public docket EPA–HQ–OPP–2010–0466 at *http://www.regulations.gov* in document ''Novaluron: Human-Health Risk Assessment for Proposed Section 3 Uses on Sweet Corn and in Food-or Feed-Handling Establishments'' on pp. 21–26.

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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA 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 2-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. 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; 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. There is minimal indication that novaluron 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 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 anticipated residues derived from reliable residue field trials, tolerance-level residues for proposed commodities, average PCT data for some commodities, and PCTn data for grain sorghum and sweet corn. 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 post-application 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 55% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. The residential exposure assessment was conducted using high-end estimates of use and potential exposure providing a conservative, health protective estimate of risk.

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 2,520 for adults and 480 for children 1–2 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-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). An intermediate-term aggregate exposure (food+drinking water+residential) assessment was not conducted since residential intermediate-term exposures are not likely due to the intermittent nature of applications by homeowners.

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 methodology (gas chromatography/electron-capture detection (GC/ECD) method and a high-performance liquid chromatography/ultraviolet (HPLC/UV) method) are 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; 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 an MRL for residues of novaluron in or on immature soybean seed at 0.01 ppm. Immature soybean seed (edamame) is not covered by soybean, seed; therefore, harmonization is not an issue for the proposed soybean use. There is no Codex MRL for peanut.

C. Revisions to Petitioned-for Tolerances

Based on analysis from the residue field trial data supporting the petition and use of the Organization for Economic Cooperation and Development tolerance calculation procedures, EPA revised the proposed tolerance on soybean, seed from 0.06 ppm to 0.07 ppm. Additionally, the commodity term for peanuts is being revised.

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 peanut and soybean, seed at 0.01 and 0.07 ppm, respectively.

This regulation additionally deletes the time-limited tolerance for strawberry, as that tolerance expired on December 31, 2011.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled

''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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: June 25, 2013.

G. Jeffrey Herndon,

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. In § 180.598:

■ a. Add alphabetically the commodities to the table in paragraph (a).

■ b. Remove and reserve paragraph (b).

§ 180.598 Novaluron; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Peanut	0.01
* * * * *	
Soybean, seed	0.07
* * * * *	

(b) *Section 18 emergency exemptions.* [Reserved]

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[FR Doc. 2013–15869 Filed 7–2–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

RIN 0906–AA73

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: HHS is issuing this final rule (herein referred to as ''this rule'') to add vascularized composite allografts (VCAs) as specified herein to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN) (herein referred to as the OPTN final rule). When it enacted the National Organ Transplant Act in 1984, Congress included a definition of the term organ and authorized the Secretary to expand this definition by regulation. The Secretary has previously exercised this authority and expanded the statutory definition of organ. Prior to this rule, the OPTN final rule defined covered organs as ''a human kidney, liver, heart, lung, or pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled 'For use in organ transplantation only.' '' This rule also includes a corresponding change to the definition of human organs covered by section 301 of the National Organ Transplant Act of 1984, as amended (NOTA).

DATES: The final rule is effective July 3, 2014.

FOR FURTHER INFORMATION CONTACT: James Bowman, M.D., Medical Director, Division of Transplantation, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857, or by telephone (301) 443–7577.

SUPPLEMENTARY INFORMATION: On December 16, 2011, HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (76 FR 78216) to include VCAs within the definition of organs covered by the OPTN final rule and to make a corresponding change to the definition of human organs covered by section 301 of NOTA. The NPRM provided for a 60-day comment period and HHS received 29 comment letters raising a variety of issues. HHS has carefully considered all comments in developing this rule, as outlined in Section III below, presenting a summary of all major comments and Departmental responses.

I. Background

As discussed in the NPRM, the transplant community has referred to the transplants of intact vascularized body parts such as hands and faces as composite tissue allograft transplants. As tissues, these components have been under the regulatory jurisdiction of the Food and Drug Administration (FDA). For the reasons outlined in the NPRM, the Secretary believes that these components, based on their clinical characteristics, are more characteristic of organs as defined specifically in NOTA and subsequently by regulation in the case of intestines and blood vessels used in conjunction with organ transplantation. For the purpose of this regulation, these components are described as vascularized composite allografts (VCAs).

Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient are regulated as human cells, tissues, and cellular and tissue-based products (or HCT/Ps). FDA regulates HCT/Ps under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR parts 1270 and 1271. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes, and semen. FDA does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung, or pancreas. FDA regulations provide that ''vascularized human organs for transplantation'' are not considered HCT/Ps. 21 CFR 1271.3(d)(1). HRSA oversees the transplantation of vascularized human organs.

At present, face and hand allografts, and other body parts meeting the proposed definition of VCAs, are not