the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: May 18, 2010.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.226 is amended as follows:

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

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

iii. Revise paragraph (a)(3);

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

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

The amendments read as follows:

§ 180.226 Diquat; tolerances for residues.

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

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

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

* * * * *

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

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

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

* * * * *

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

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0273; FRL–8825–3]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective May 26, 2010. Objections and requests for hearings must be received on or before July 26, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).
• Food manufacturing (NAICS code 311).
• Pesticide manufacturing (NAICS code 32532).

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

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

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0273 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 26, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0273, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of June 10, 2009 (74 FR 27538) (FRL–8417–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7547) by Makhteshim-Agan of North America, Inc., 4515 Falls of Neuse Road, Raleigh, NC 27609. 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 sorghum, grain at 3 parts per million (ppm); sorghum, aspirated grain fractions at 25 ppm; sorghum, forage at 6 ppm; and sorghum, stover at 40 ppm. Additionally, the petition requested to amend existing tolerances of novaluron in or on poultry, fat from 0.40 ppm to 7.0 ppm; poultry, meat from 0.03 ppm to 0.40 ppm; poultry, meat byproducts from 0.04 ppm to 0.80 ppm; hog, fat from 0.05 ppm to 1.5 ppm; hog, meat from 0.01 ppm to 0.07 ppm; hog, meat byproducts from 0.01 ppm to 0.15 ppm; and eggs from 0.05 ppm to 1.5 ppm. That notice referenced a summary of the petition prepared by Makhteshim-Agan of North America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance for hog, meat byproducts and has additionally determined that individual tolerances on poultry, liver; poultry, kidney; hog, liver; and hog, kidney are necessary. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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 (toxicity to blood) such as methemoglobinemia, decreased hemoglobin, decreased hematocrit, and decreased 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 an 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 hematotoxicity.

Clinical signs of neurotoxicity and neuropathology 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 addition, there were no clinical signs of toxicity observed in the acute oral toxicity study with novaluron (LD_{50} >5,000 milligrams/kilogram (mg/kg)). 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 and no evidence of mutagenic activity in the submitted mutagenicity studies, including a bacterial (*Salmonella, E. coli*) reverse mutation assay, an *in vitro* mammalian chromosomal aberration assay, an *in vivo* mouse bone-marrow micronucleus assay and a bacterial DNA damage/repair assay. Based on the results of these studies, EPA has classified novaluron 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 Use on Grain Sorghum." at pages 27–30 in docket ID number EPA–HQ–OPP–2009–0273.

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 the following Table.

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR NOVALURON FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	Not applicable	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 and turnover resulting in a regenerative anemia.

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose. RfD = reference dose. LOC = level of concern.

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 United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA incorporated average percent crop treated (PCT) data for apples, cabbage, cotton, pears, and potatoes and estimated PCT data for the new use on sorghum; 100 PCT was assumed for the remaining food commodities. The Agency utilized anticipated residues (ARs) for most commodities, including meat, milk, hog, and poultry commodities. Average field trial residues were used for pome fruit, sugarcane, bushberry, *Brassica* leafy greens, stone fruit, bell pepper, nonbell pepper, cucumber, summer squash, cantaloupe, strawberry, succulent snap bean, dry bean seed, and Swiss chard, and average greenhouse trial residues for tomato. Empirical processing factors

for apple juice (translated to pear and stone fruit juice), tomato paste and puree, and Dietary Exposure Evaluation Model (DEEM) default processing factors for the remaining processed commodities were used to estimate anticipated residues in processed foods.

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:

Apples at 15%; cabbage at 10%; cotton at 2.5%; pears at 10%; and potatoes at 2.5%.

In most cases, EPA uses available data from USDA/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 new uses as follows:

Grain sorghum at 5%.

EPA utilized estimated PCT data in the chronic dietary risk assessment for the new use on grain sorghum, based on the market leader approach. The market leader approach is the comparison of the PCT with all chemicals of a specific type (i.e., herbicide, insecticide, etc.) on a specific crop and choosing the highest PCT (market leader) as the PCT for the new use. 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 5 years of actual use. The predominant factors that bear on whether the estimated PCT 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 has a relatively narrow spectrum of activity compared to the market leaders and specifically targets *lepidopterous* insects, which are not key pests of grain sorghum. Additionally, there are no resistance or pest pressure issues identified for the use of novaluron on grain sorghum. All information currently available has been considered for use on grain sorghum, and EPA concludes that it is unlikely that the actual grain sorghum PCT with 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 its 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*.

The following models were used to assess residues of concern in drinking water: The Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) for parent novaluron in surface water; the First Index Reservoir Screening Tool (FIRST) for chlorophenyl urea and chloroaniline degradates in surface water; and the Screening Concentration in Ground Water (SCI-GROW) model for novaluron, chlorophenyl urea and chloroaniline in ground water. The estimated drinking water concentrations (EDWCs) of novaluron, chlorophenyl urea, and chloroaniline for chronic exposures for non-cancer assessments are estimated to be 0.76 parts per billion (ppb), 0.89 ppb and 2.6 ppb, respectively, for surface water and 0.0056 ppb, 0.0045 ppb and 0.0090 ppb, respectively, for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The

highest drinking water concentrations were estimated for surface water. Of the three EDWC values for surface water, the chronic EDWC for the terminal metabolite, chloroaniline, is the highest (assuming 100% molar conversion from parent to aniline). This is consistent with the expected degradation pattern for novaluron. Therefore, for chronic dietary risk assessment, the water concentration value for chloroaniline of 2.6 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 not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found 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 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 reproduction study, 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 except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. Although effects were seen in the spleen in two studies, as explained in Unit III.A., EPA has concluded that novaluron does not directly target the immune system and the Agency does not believe that conducting a functional immunotoxicity study will result in a NOAEL lower than the regulatory dose for risk assessment; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There were signs of neurotoxicity in the acute neurotoxicity study in rats, including clinical signs (piloerection, fast/irregular breathing), functional observation battery (FOB) parameters (head swaying, abnormal gait), and neuropathology (sciatic and tibial nerve degeneration). However, the signs observed were not severe, were seen only at the limit dose (2,000 mg/kg/day) and were not reproducible. No signs of neurotoxicity or neuropathology were observed in the subchronic neurotoxicity study in rats at doses up to 1,752 mg/kg/day in males and 2,000 mg/kg/day in females or in any other subchronic or chronic toxicity study in rats, mice or dogs, including the developmental and reproduction studies. In addition, no clinical signs of toxicity were observed in the acute oral toxicity study (LD_{50} > 5,000 mg/kg). Therefore, novaluron does not appear to be a neurotoxicant, 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. Although storage stability data has been requested for grain sorghum forage, grain, and stover, there are no residual uncertainties identified in the exposure databases because acceptable storage stability data is available for various commodities which demonstrate the stability of novaluron in/or on food commodities for up to 15.3 months, which exceeds the longest storage time (9.0 months for grain sorghum forage) of the grain sorghum commodities in the field trials. The chronic dietary food exposure assessment utilized tolerance level residues or anticipated residues that are based on reliable field trial data, and reliable data from processing studies or worst case assumptions. The chronic assessment also utilized PCT data (average PCT for several currently registered commodities and estimated PCT data for the new use on grain sorghum), which have a valid basis and are considered to be reliable. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to novaluron in drinking water. Residential exposures are not expected. 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 32% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for novaluron.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short- or intermediate-term adverse effect was identified, novaluron is not expected to pose a short- or intermediate-term risk.

4. *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.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The following adequate enforcement methodologies are available to enforce the tolerance expression: A gas chromatography/electron-capture detection (GC/ECD) method and a high-performance liquid chromatography/ultraviolet (HPLC/UV) method. 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; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits (MRLs) established for residues of novaluron in or on grain sorghum commodities associated with this petition. There are Codex MRLs established for poultry, meat; poultry, edible offal of; and eggs at 0.01 ppm; and meat (mammalian other than marine) at 10 ppm. Additionally, there are Canadian MRLs established for meat of hogs and meat byproducts of hogs at 0.01 ppm. EPA's analysis of data used to determine the secondary residues in animal commodities, including the dietary burden in the United States for registered/proposed uses of novaluron, supports establishing tolerances in poultry, meat at 0.40 ppm; poultry, liver and kidney at 0.8 ppm; hog, meat at 0.07 ppm; and egg at 1.5 ppm. Therefore, U.S. tolerances on these animal commodities cannot be harmonized with the associated Codex or Canadian MRLs.

C. Revisions to Petitioned-For Tolerances

Based on analysis of the data supporting the petition, EPA has revised the proposed tolerance for hog, meat byproducts from 0.15 ppm to 0.10 ppm. Additionally, the Agency has determined that individual tolerances on poultry, liver at 0.80 ppm; poultry, kidney at 0.80 ppm; hog, liver at 0.10 ppm; and hog, kidney at 0.10 ppm are necessary. These revisions are based on the following:

Several tolerances for secondary residues in animal commodities have been established for novaluron based on reasonably balanced dietary burdens (RBDBs) derived from feedstuff percentages. However, new RBDBs have been established based on the proposed/established uses of novaluron, thus necessitating revisions in the proposed/established tolerances for secondary residues in or on poultry and hog commodities. Therefore, the Agency has revised the proposed tolerance for hog, meat byproducts from 0.15 ppm to 0.10 ppm and has determined that individual tolerances are necessary for hog, liver and hog, kidney at 0.10 ppm; and poultry, liver and poultry, kidney at 0.80 ppm.

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 sorghum, grain, grain at 3.0 ppm; grain, aspirated fractions at 25 ppm; sorghum, grain, forage at 6.0 ppm; sorghum, grain, stover at 40 ppm; poultry, fat at 7.0 ppm; poultry, meat at 0.40 ppm; poultry, liver at 0.80 ppm; poultry, kidney at 0.80 ppm; poultry, meat byproducts at 0.80 ppm; hog, fat at 1.5 ppm; hog, meat at 0.07 ppm; hog, liver at 0.10 ppm; hog, kidney at 0.10 ppm; hog, meat byproducts at 0.10 ppm; and egg at 1.5 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: May 14, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.598 is amended in paragraph (a) as follows:

i. Add alphabetically "Grain, aspirated fractions"; "Hog, kidney"; "Hog, liver"; "Poultry, kidney"; "Poultry, liver"; "Sorghum, grain, forage"; "Sorghum, grain, grain"; and "Sorghum, grain, stover" to the table; and

ii. Revise the entries for "Egg"; "Hog, fat"; "Hog, meat"; "Hog, meat byproducts"; "Poultry, fat"; "Poultry, meat"; and "Poultry, meat byproducts." The added and revised entries to read as follows:

§180.598 Novaluron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Egg	1.5
* * *	* *
Grain, aspirated fractions	25
* * *	* *
Hog, fat	1.5
Hog, kidney	0.10
Hog, liver	0.10
Hog, meat	0.07
Hog, meat byproducts	0.10
* * *	* *
Poultry, fat	7.0
Poultry, kidney	0.80
Poultry, liver	0.80
Poultry, meat	0.40
Poultry, meat byproducts	0.80
* * *	* *
Sorghum, grain, forage	6.0
Sorghum, grain, grain	3.0
Sorghum, grain, stover	40
* * *	* *

* * * * *

[FR Doc. 2010–12649 Filed 5–25–10; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 5a

RIN 0906–AA86

Public Health Service Act, Rural Physician Training Grant Program, Definition of "Underserved Rural Community"

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

ACTION: Interim final rule with request for comment.

SUMMARY: This interim final rule (IFR) with request for comment is meant to comply with the statutory directive to issue a regulation defining "underserved rural community" for purposes of the Rural Physician Training Grant Program in section 749B of the Public Health Service Act, as amended by the Patient Protection and Affordable Care Act of 2010. This IFR is technical in nature. It will not change grant or funding eligibility for any other grant program currently available through the Office of Rural Health Policy (ORHP) or HRSA. For purposes of the Rural Physician Training Grant Program only, HRSA has combined existing definitions of "underserved" and "rural" by using the definition of rural utilized by the ORHP Rural Health Grant programs and the definition of "underserved" established by HRSA's Office of Shortage Designation (OSD) in the Bureau of Health Professions (BHPr).

DATES: *Effective Date:* This interim final rule is effective 30 days after May 26, 2010.

Comment Date: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on July 26, 2010.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: mgoodman@hrsa.gov.* Include RIN 0906–AA86 in the subject line of the message.
- *Mail:* Michelle Goodman, MAA, Office of Rural Health Policy, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, 10B–45, Rockville, MD 20857.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All comments received will be available for public inspection and copying, including any personal information provided, at Parklawn Building, 5600 Fishers Lane, Room 10B–45, Rockville, Maryland 20857, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Michelle Goodman, MAA, at the mail or e-mail address above or by telephone at 301–443–0835.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The ORHP was authorized in December 1987 through Public Law 100–203 and is located in the HRSA. Congress charged ORHP with informing and advising HHS on matters affecting rural hospitals and health care and