

acid), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the sum of the residues of dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite, 3,6-dichloro-5-hydroxy-*o*-anisic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

Commodity	Parts per million
* * * *	*
Teff, forage .....	90.0
Teff, grain .....	6.0
Teff, hay .....	40.0
Teff, straw .....	30.0
* * * *	*

(2) Tolerances are established for residues of the herbicide dicamba, 3,6-dichloro-*o*-anisic acid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite, 3,6-dichloro-2-hydroxybenzoic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

\* \* \* \*

(3) Tolerances are established for residues of the herbicide dicamba, 3,6-dichloro-*o*-anisic acid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of dicamba, 3,6-dichloro-*o*-anisic acid, and its metabolites, 3,6-dichloro-5-hydroxy-*o*-anisic acid, and 3,6-dichloro-2-hydroxybenzoic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

\* \* \* \*

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BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2010-0466; FRL-8882-1]

**Novaluron; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances under the Federal Food,

Drug, and Cosmetic Act (FFDCA) for residues of novaluron in or on multiple commodities which are identified and discussed later in this document. Additionally, the Agency is amending existing tolerances for meat byproducts and revising commodity terms for hog and poultry byproducts. Interregional Research Project Number 4 (IR-4) requested the sweet corn tolerances; Makhteshim-Agan of North America, Inc. requested the food and feed handling establishment tolerances.

**DATES:** This regulation is effective September 9, 2011. Objections and requests for hearings must be received on or before November 8, 2011, 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-2010-0466. 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:** 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; *e-mail address:* [gaines.jennifer@epa.gov](mailto: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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0466 in the subject line on the first page of your. All requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 8, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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

EPA-HQ-OPP-2010-0466, by one of the following methods:

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

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

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

## II. Summary of Petitioned-for Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL-8831-3), 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 0F7708) by Makhteshim-Agan of North America, Inc., 4515 Falls of Neuse Road, Raleigh, NC 27609 as well as the filing of a pesticide petition (PP 0E7723) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The IR-4 petition (PP 0E7723) 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 corn, sweet, kernels plus cob with husks removed at 0.05 parts per million (ppm); corn, sweet, forage at 20 ppm; and corn, sweet, stover at 50 ppm and to increase the established livestock tolerances for residues of novaluron in or on milk from 1.0 to 1.5 ppm, and milk fat from 20 to 35 ppm, respectively. The Makhteshim-Agan petition (PP 0F7708) requested novaluron tolerances for all food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments where food products are held, processed or prepared at 0.01 ppm. That notice referenced a summary of the petitions 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 for PP 0F7708. Comments were received on the notice of filing for PP 0E7723. EPA's response

to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerances for sweet corn forage and determined it is not appropriate to raise the existing tolerances for milk and milk fat. The EPA also determined it is appropriate to revise several existing livestock commodities based on the proposed sweet corn use. The reasons for these changes are explained in Unit IV.D.

## III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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. No ocular or dermal irritation was

noted. Novaluron 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 red blood corpuscles (RBCs or erythrocytes) that were associated with compensatory 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 two-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 increase age at preputial separation in the F1 generation) was observed at a higher dose only in males.

Signs of neurotoxicity were seen in the rat acute neurotoxicity study at the limit dose, including clinical signs (piloerection, fast/irregular breathing), functional observation battery (FOB) parameters (head swaying, abnormal gait) and neuropathology (sciatic and tibial nerve degeneration). However, no signs of neurotoxicity or neuropathology were observed in the subchronic neurotoxicity study in rats 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 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 or 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 Uses on Sweet Corn and in Food—or Feed-Handling Establishments" at pages 53–56 in docket ID number EPA-HQ-OPP-2010-0466.

**B. Toxicological Points of Departure/ Levels of Concern**

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful

analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some

degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for novaluron used for human risk assessment is shown in Table 1 of this unit.

**TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR NOVALURON FOR USE IN HUMAN HEALTH RISK ASSESSMENT**

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (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 = 100. FQPA SF = 1x	Chronic RfD = 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.
Dermal short-term (1 to 30 days).	Not applicable .....	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).	Oral study NOAEL = 4.38 mg/kg/day (dermal absorption rate = 100%).	Residential 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 hematopoieses and hemosiderosis in spleen and liver).
Inhalation short-term (1 to 30 days).	Oral study NOAEL = 4.38 mg/kg/day (inhalation absorption rate = 100%).	Residential/Occupational 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 hematopoieses and hemosiderosis in spleen and liver).
Inhalation Intermediate-term (1 to 6 months).	Oral study NOAEL = 1.1 mg/kg/day (inhalation absorption rate = 100%).	Residential/Occupational LOC for MOE < 100.	Combined chronic toxicity/carcinogenicity feeding in rat. LOAEL = 30.6 mg/kg/day based on erythrocyte damage and turnover resulting in a regenerative anemia.
Cancer .....	Not likely to be carcinogenic to humans.		

UF = Uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population-adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, 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 USDA from 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA conducted a partially refined dietary (food and drinking water) exposure and risk assessment for the proposed new uses on sweet corn and in food—and feed—handling establishments, all established uses, and drinking water using the DEEM–FCID (Dietary Exposure Evaluation Model-Food Commodity Ingredient Database), Version 2.03,

which uses food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA incorporated average percent crop treated (PCT) data for apples, cabbage, cotton, pears, and potatoes, and utilized percent crop treated for new use PCT estimates 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 using average field trial residues, PCT estimates for sweet corn and grain sorghum, average PCT for apple and cotton, and assumed 100 PCT for sugarcane and cowpea seed.

The chronic analysis also incorporated average greenhouse trial residues for tomatoes; empirical processing factors for apple juice (translated to pear and stone fruit juice), cottonseed oil, dried plums, and tomato paste and puree; and DEEM default processing factors for the remaining processed commodities; and average field trial residues for all crops unless residues were less than LOQ (If residues were less than LOQ, the chronic analysis assumed 1/2 LOQ values)

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

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 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:

Sweet corn at 59% and sorghum at 5%.

EPA utilized estimated PCT data in the chronic dietary risk assessment for the new use on sweet corn and sorghum, based on the market leader approach. Sorghum, though not new, was only registered 1 year ago. Since sorghum has been registered for such a relatively short period, EPA has sorghum to be a “new use” when estimating the PCT. 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 the 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. Additionally, there are no resistance or pest pressure issues identified for the use of novaluron on

sweet corn. All information currently available has been considered for use on sweet corn, and EPA concludes that it is unlikely that the actual sweet corn 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 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>.

Estimated drinking water concentrations (EDWCs) were not generated for the food-and-feed handling establishment uses because the use pattern is not expected to result in the contamination of drinking water. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) for parent novaluron in surface water; and the Screening Concentration in Ground Water (SCI-GROW) models for novaluron, chlorophenyl urea and

chloroaniline in ground water, the 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 currently registered for any specific use patterns that would result in residential exposure. However, the following uses that could result in residential exposures are pending registration and have been assessed: Indoor and outdoor uses for the control of roaches and crickets (crack 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. There is also a potential for exposure from entering novaluron-treated areas that could lead to exposures to adults and children. Both residential handler and post-application scenarios were assessed for the indoor use since this is believed to cover the outdoor perimeter treatment. Residential handler dermal and inhalation exposures were assessed for application via low-pressure handwands and trigger-pump sprayers.

Additionally exposure routes were assessed for post-application exposures for adults and children via inhalation and dermal routes and post-application incidental oral (hand-to-mouth) exposure for children (3 to < 6 years old). Additionally, a combined residential assessment that consisted of adult dermal and inhalation post-

application exposures as well as children (3 to < 6 years old) dermal, inhalation, and oral (hand-to-mouth) post-application exposure was included which 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. 28-37.

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 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 and a 90-day inhalation toxicity study. 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. A 90-day inhalation toxicity study is requested for further characterization of inhalation risk. Due to the potential for repeated inhalation exposure anticipated from the proposed residential use pattern, there is concern for toxicity by the inhalation route. An inhalation study would provide a dose and endpoint via the route of exposure of concern (*i.e.* route-specific study) and thus would avoid using an oral study and route-to-route extrapolation. Although a point of departure from an oral study was used to assess residential post-application inhalation risks for novaluron, the Agency does not believe this assessment is under-protective. The

post-application inhalation MOEs calculated were all greater than 3,000, thus providing an ample margin of safety to account for any uncertainties in route-to-route extrapolation. Further, the MOE was calculated for post-application inhalation exposure and risk using the saturation concentration which is a very conservative approach. The saturation concentration represents what would occur if a large amount of chemical were spilled in a non-ventilated room and allowed to evaporate until equilibrium is reached.

ii. There were signs of neurotoxicity in the acute neurotoxicity study in rats, including clinical signs (piloerection, irregular breathing), functional observation battery (FOB) parameters (increased 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 (2000 mg/kg/day) and were not reproducible. No signs of neurotoxicity or neuropathology were observed in the subchronic neurotoxicity study in rats at similar doses, and no evidence of neuropathology was observed in subchronic and chronic toxicity studies in rats, mice, or dogs. In addition, no clinical signs were observed in the acute oral toxicity study ( $LD_{50} \leq 5,000$  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. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using anticipated residues derived from reliable residue field trials and PCT assumptions for some commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to novaluron in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers resulting from the proposed residential uses of novaluron. 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 72% 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).

There are potential short-term exposures from the pending residential uses for novaluron. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to novaluron.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,600 for the U.S. population and 290 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).

There are potential intermediate-term exposures from the pending residential uses for novaluron. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to novaluron.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 320 for U.S. population and 140 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.

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

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

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for residues of novaluron in or on sweet corn, stover,

forage and kernel plus cob with husks removed or for all food commodities based on the use of novaluron in food and feed handling establishments. Canada is currently in the process of reviewing the use of novaluron on sweet corn. The EPA and the Pest Management Regulatory Agency (PMRA) reviewed the sweet corn petition as a Joint Review Project and tolerance recommendations are in agreement at 0.05 ppm for sweet corn and kernel plus cob with husks removed. Additionally, PMRA proposed to increase its MRL for milk to 1.0 ppm from 0.5 ppm, and as a result the EPA and PMRA milk tolerances/MRLs will be in agreement. The PMRA does not recommend MRLs for livestock feed commodities and therefore will not establish MRLs for sweet corn stover and sweet corn forage.

### C. Response to Comments

EPA received one comment to the Notice of Filing that made a general objection to the presence of any novaluron residues on vegetable crops. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. The commenter also expressed concern that EPA's risk assessment for novaluron did no "combined testing" with other chemicals. EPA, however, does not require "combined testing" of a pesticide with other pesticides or other chemicals due to impracticality. With regard to the potential for cumulative effects from exposure to the pesticide and other substances with a common mechanism of toxicity, see the discussion of this issue in Unit III.C.4., *Cumulative effects from substances with a common mechanism of toxicity*.

### D. Revisions to Petitioned-for Tolerances

Based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*, EPA revised the proposed tolerance on

corn, sweet, forage from 20 ppm to 16 ppm and determined no change to the existing milk and milk fat tolerances is needed.

Based on the proposed use on sweet corn, the revised reasonably balanced dietary burdens (RBDBs) for novaluron are 9.6 ppm for beef cattle, 18.3 ppm for dairy cattle, 2.4 ppm for poultry, and 2.5 ppm for swine. Accordingly, the Agency has determined it is appropriate to raise the existing tolerances for meat byproducts. However, no changes are necessary for the tolerances for secondary residues in/on cattle, goat, horse, sheep, poultry, and swine commodities. Additionally, commodity terms for hog, meat byproducts and poultry, meat byproducts are being revised.

Therefore, the tolerances for meat byproducts are being revised as follows: Cattle, meat byproducts, except kidney and liver from 0.60 ppm to 11 ppm; goat, meat byproducts, except kidney and liver from 0.60 ppm to 11 ppm; horse, meat byproducts, except kidney and liver from 0.60 ppm to 11 ppm; sheep, meat byproducts, except kidney and liver from 0.60 ppm to 11 ppm; hog, meat byproducts from 0.10 ppm to hog, meat byproducts, except kidney and liver to 1.5 ppm; and poultry, meat byproducts from 0.80 ppm to poultry, meat byproducts, except kidney and liver to 7.0 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 corn, sweet, kernels plus cob with husks removed at 0.05 ppm; corn, sweet, forage at 16 ppm; corn, sweet, stover at 50 ppm; cattle, meat byproducts, except kidney and liver at 11 ppm; goat, meat byproducts, except kidney and liver at 11 ppm; horse, meat byproducts, except kidney and liver at 11 ppm; sheep, meat byproducts, except kidney and liver at 11 ppm; hog, meat byproducts, except kidney and liver at 1.5 ppm; poultry, meat byproducts, except kidney and liver at 7.0 ppm; and Food/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments at 0.01 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) (Pub. L. 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995

(NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: August 26, 2011.

**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, paragraph (a), is amended as follows:  
  - a. Revise the commodity entries for “cattle, meat byproducts, except kidney and liver”; “goat, meat byproducts, except kidney and liver”; “hog, meat byproducts”; “horse, meat byproducts, except kidney and liver”; “poultry, meat byproducts”; “sheep, meat byproducts, except kidney and liver”; and
  - b. Add, alphabetically, the commodities for “corn, sweet, forage”; “corn, sweet, kernel plus cob with husks removed”; “corn, sweet, stover”; and “food and feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food and feed handling establishments.”

The revised and added text reads as follows:

**§ 180.598 Novaluron; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Cattle, meat byproducts, except kidney and liver .....	11

Commodity	Parts per million
* * * * *	*
Corn, sweet, forage .....	16
Corn, sweet, kernel plus cob with husks removed .....	0.05
Corn, sweet, stover .....	50
* * * * *	*
Food commodities and feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food and feed handling establishments .....	0.01
* * * * *	*
Goat, meat byproducts, except kidney and liver .....	11
* * * * *	*
Hog, meat byproducts, except kidney and liver .....	1.5
* * * * *	*
Horse, meat byproducts, except kidney and liver .....	11
* * * * *	*
Poultry, meat byproducts, except kidney and liver .....	7.0
* * * * *	*
Sheep, meat byproducts, except kidney and liver .....	11

\* \* \* \* \*  
 [FR Doc. 2011–22981 Filed 9–8–11; 8:45 am]  
**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**  
**[EPA–HQ–OPP–2010–0905; FRL–8881–7]**

**2,4-D; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).  
**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of 2,4-D in or on teff, bran; teff, forage; teff, grain; and teff, straw. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 9, 2011. Objections and requests for hearings must be received on or before November 8, 2011, 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–2010–0905. 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](mailto: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**.