ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0438 FRL–8391–5]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on sugarcane, cane and tomato. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). It also revokes the existing, time-limited tolerance for residues of novaluron in or on sugarcane, cane and revises the chemical name for novaluron in 40 CFR 180.598 to reflect EPA's preferred nomenclature.

DATES: This regulation is effective December 10, 2008. Objections and requests for hearings must be received on or before February 9, 2009, 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–2007–0438. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

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–2007–0438 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 9, 2009.

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–2007–0438, 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 July 25, 2007 (72 FR 40877) (FRL–8137–1), 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 7E7199) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton NJ 08540. The petition requested that 40 CFR 180.598 be amended by establishing tolerances for residues of the insecticide novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea, in or on sugarcane, cane at 0.50 parts per million (ppm); tomato at 0.40 ppm; and tomato, paste at 0.80 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Makhteshim-Agan of North America, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has increased the tolerance on tomato to 1.0 ppm and determined that a separate tolerance on tomato, paste is not needed. 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 the petitioned-for tolerances for residues of novaluron on sugarcane, cane at 0.50 ppm and tomato at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

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

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 maternal and offspring toxicity were evidenced by spleenomegaly. Reproductive toxicity (decreases in epididymal sperm counts and increased age at preputial separation in the F1 generation) was observed only in males.

Novaluron does not appear to be a potent neurotoxicant. Signs of neurotoxicity were seen in the acute neurotoxicity study in rats but only at the limit dose of 2,000 milligrams/kilogram/day (mg/kg/day). Neurotoxic signs seen in this study included clinical signs (piloerection, fast/irregular breathing), functional observation battery (FOB) parameters (head swaying, abnormal gait) and neuropathology (sciatic and tibial nerve degeneration). 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.

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 bacterial DNA damage or repair assay. Based on the results of these studies, EPA has classified novaluron as ''not likely to be carcinogen 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 *PP 7E7199 Novaluron in/on Sugarcane and Tomato. Health Effects Division (HED) Risk Assessment*, pages 24 to 27 in docket ID number EPA–HQ–OPP–2007–0438.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which the NOAEL are observed in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL concern are identified or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in document *PP-7E7199 Novaluron in/on Sugarcane and Tomato. Health Effects Division (HED) Risk Assessment*, pages 10 to 11 in docket ID number EPA–HQ–OPP–2007–0438.

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 anticipated residues (average field trial residues) for some commodities, including the new commodities (sugarcane and tomatoes); empirical processing factors for apple juice (translated to pear juice); and DEEM (ver 7.81) default processing factors for the remaining processed commodities. In estimating dietary exposure from secondary residues in livestock, EPA relied on anticipated residues for meat and milk commodities but used tolerance-level residues for poultry commodities. 100 percent crop treated (PCT) was assumed for all existing and new uses of novaluron.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA has classified novaluron as ''not likely to be carcinogenic to humans;'' therefore, a quantitative cancer exposure assessment is unnecessary.

iv. *Anticipated residue 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.

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*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of novaluron, chlorophenyl urea and chloroaniline for chronic exposures for non-cancer assessments are estimated to be 1.8 parts per billion (ppb), 0.86 ppb and 2.6 ppb, respectively, for surface water and 0.0055 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 percent 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 of 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 maternal toxicity (increased absolute and relative spleen weights) were similar and occurred at the same dose; and 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 maternal 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. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect after the tolerance petition was submitted, these studies are not yet available for novaluron. In the absence of specific immunotoxicity studies, EPA has evaluated the available novaluron toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the

immune system at the LOAEL in any study novaluron. In addition, novaluron does not belong to a class of chemicals (*e.g.*, the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a point of departure less than the NOAEL of 0.011 mg/kg/day used in calculation the cPAD for novaluron, and 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 and were seen only at the limit dose (2,000 mg/kg/day); further, the neuropathological effects that were seen at the limit dose also occurred in a few untreated control animals. 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. Therefore, novaluron does not appear to cause significant neurotoxicant effects, 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 based on 100% CT and tolerance-level or anticipated residues derived from reliable residue field trials. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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 74% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of novaluron is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Novaluron is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to novaluron through food and water and will not be greater than the chronic aggregate risk.

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). Novaluron is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to novaluron through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. EPA has classified novaluron as ''not likely to be carcinogenic to humans.''Novaluron is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a gas chromatography/electron-capture detection (GC/ECD) method; and a high pressure liquid chromatography/ ultraviolate detection (HPLC/UV) method) is 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*.

B. International Residue Limits

No Canadian or Mexican MRLs have been established for novaluron on the sugarcane or tomato commodities. A CODEX MRL is established for novaluron (fat soluble) on tomato at 0.02 ppm, significantly below the U.S. tolerance being established by this regulation (1.0 ppm). The U.S. tolerance is based on a different use pattern, including both a higher application rate (12.8x higher) and shorter pre-harvest interval (PHI) (2 days vs. 7 days). For these reasons, the U.S. tolerance cannot be harmonized with the CODEX MRL at this time.

C. Response to Comments

EPA received comments from a private citizen complaining that she was unable to open the ''proposal'' at *http://www.regulations.gov*. If by ''proposal,'' the commenter is referring to the registrant's notice of filing, EPA notes that it is available in the docket in two common file formats, MicroSoft Word and Portable Document Format (PDF) and cannot explain the commenter's inability to open it. User support is available for anyone having trouble using the regulations website by calling 1–877-ERUL HLP (1–877–378–5457) or by using the Web form link provided under ''Contact Us.''

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerance on tomato should be increased to 1.0 ppm and that a separate tolerance on tomato paste is not needed. EPA revised the tolerance level for tomato based on analyses of both field- and greenhouse-

grown residue trials using the Agency's Tolerance Spreadsheet in accordance with the *Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. The tolerance level of 1.0 ppm is based on the spreadsheet results for greenhouse-grown tomatoes, the cropping scenario that resulted in the higher recommended tolerance. The submitted tomato processing data indicate that residues of novaluron are not likely to concentrate in puree but may concentrate slightly in paste. Based on the processing factor (1.1x) for paste and the highest average field trial (HAFT) residue of 0.365 ppm from the tomato trials, residues of novaluron in paste are not expected to exceed the tolerance for tomato (1.0 ppm); therefore, no tolerances for tomato processed commodities are needed.

The tolerance expression at 40 CFR 180.598 uses the International Union of Pure and Applied Chemistry (IUPAC) nomenclature for novaluron (1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoro-methoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea). Since it is EPA's policy to use the Chemical Abstracts Service (CAS) nomenclature in tolerance expressions, EPA is revising the tolerance expression to reflect the correct CAS designation for novaluron (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy] phenyl]amino]carbonyl]-2,6-difluorobenzamide). EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is a minor change in scientific nomenclature consistent with accepted Agency policy and practice.

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 sugarcane, cane at 0.50 ppm and tomato at 1.0 ppm.

A time-limited tolerance of 0.15 ppm was established for residues of novaluron on sugarcane, cane in connection with a FIFRA section 18 emergency exemption granted by EPA. This tolerance (set to expire on 12/31/09) is superseded by the higher tolerance being established on sugarcane, cane and is no longer needed. Therefore, the time-limited tolerance is being revoked.

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: November 25, 2008.

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 by removing the entry for sugarcane, cane from the table in paragraph (b); revising paragraph (a) introductory text and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) *General.* Tolerances are established 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 the following raw agricultural commodities:

Commodity	Parts per million
* * * * *	
Sugarcane, cane	0.50
Tomato	1.0
* * * * *	

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[FR Doc. E8–29117 Filed 12–9–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 220, 221, 222, 223, 224, 227, and 228

[FRL–8748–4]

RIN 2040–AF01

Repeal of Obsolete Regulations Under the Marine Protection, Research, and Sanctuaries Act Regarding Interim Ocean Dumping Sites, Interim Ocean Dumping Permits, and Interim Ocean Dumping Criteria

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to repeal expired, and therefore, obsolete regulatory provisions regarding interim ocean dumping sites, interim ocean dumping permits, and interim ocean dumping criteria. Repeal of all reference to ''interim'' provisions is necessary based on legislation enacted since promulgation of the reference, EPA action since promulgation of the reference, or the passage of a date specified in a definition of the reference. This action does not make any substantive changes to EPA's ocean dumping regulations. This is a housekeeping measure intended only to eliminate confusion by repealing obsolete regulatory text.

DATES: This rule is effective on January 9, 2009.

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SUPPLEMENTARY INFORMATION:

I. Overview

Amendments enacted in 1992 to the Marine Protection, Research, and Sanctuaries Act (MPRSA) require that no permits for ocean dumping shall be issued for an EPA-established ocean dumping site after January 1, 1997, unless the site has received a final designation; therefore, interim ocean dumping sites that have not received a final designation are no longer available for use. Under EPA regulations, the authority to issue interim ocean dumping permits expired on April 23, 1978, and interim permits are no longer issued. Under EPA regulations, interim criteria for constituents prohibited as other than trace contaminants in material proposed for ocean dumping, as well as interim guidance used to determine the limiting permissible concentration for the suspended particulate and solid phases of the material proposed to be dumped, were applicable only until EPA announced the availability of acceptable procedures to evaluate materials for ocean dumping. On April 4, 1991, EPA and the U.S. Army Corps of Engineers announced the availability of a testing manual for dredged material entitled ''Evaluation of Dredged Material Proposed for Ocean Disposal—Testing Manual,'' which revised the 1977 EPA/U.S. Army Corps of Engineers document, ''Ecological Evaluation of Proposed Discharge of Dredged Material into Ocean Waters.'' In addition, EPA published ''Bioassay Procedures for the Ocean Disposal Permit Program,'' which outlines acceptable procedures for non-dredged material.

II. Background

A. Potentially Affected Entities

Generally, ocean dumping sites and permits are used by persons, organizations, or government bodies seeking to dispose of dredged material or other material in ocean waters. However, there are no regulated entities potentially affected by this action, because all of the regulatory provisions being repealed have expired, and therefore, have become obsolete (see Section III below). Nothing in this action alters the jurisdiction or authority of EPA or the entities regulated under the Marine Protection, Research, and Sanctuaries Act.

B. Marine Protection, Research, and Sanctuaries Act

The Marine Protection, Research, and Sanctuaries Act of 1972, as amended, also known as the Ocean Dumping Act, regulates the transportation and dumping of material into ocean waters. Under the MPRSA, no permit may be issued for ocean dumping where such dumping will unreasonably degrade or endanger human health or the marine environment. Most material ocean dumped today is dredged material (i.e., sediments) removed from the bottom of water bodies to maintain navigation channels and berthing areas. Other materials that are currently disposed of in the ocean include fish wastes, human remains, and vessels.

Ocean dumping cannot occur except pursuant to a permit under the MPRSA and its implementing regulations. The U.S. Army Corps of Engineers (USACE) issues permits for dumping dredged material in the ocean, using EPA's environmental criteria and subject to EPA's concurrence. For all other materials, EPA is the permitting agency. EPA also is responsible for designating recommended ocean dumping sites for all types of materials, including dredged material. EPA's ocean dumping regulations at 40 CFR Part 228 establish procedures for the designation and management of ocean disposal sites and list the available EPA-designated ocean dumping sites by EPA Region (40 CFR 228.15).

C. Interim Ocean Dumping Sites, Permits, Criteria, and Guidance

When EPA originally promulgated the ocean dumping regulations in the 1970's, the Agency made provisions for interim ocean dumping sites, interim ocean dumping permits, and interim ocean dumping criteria. These interim provisions were designed to be temporary measures that would expire under certain conditions, primarily when final sites were designated and criteria were established. As described in Section III below, all provisions related to interim ocean dumping sites, interim permits, interim criteria, and interim guidance have expired and are therefore obsolete.