ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0815; FRL–8098–8]

Novaluron; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of novaluron in or on sugarcane. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarcane. This regulation establishes a maximum permissible level for residues of novaluron in this food commodity. The tolerance expires and is revoked on December 31, 2009.

DATES: This regulation is effective October 20, 2006. Objections and requests for hearings must be received on or before December 19, 2006, 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-2006-0815. All documents in the docket are listed on the regulations.gov website. 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9356; e-mail address: *conrath.andrea@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:

- 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 provides 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 an electronic copy of this **Federal Register** document through the electronic docket 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2006-0815 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 on or before December 19, 2006.

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 your copies, identified by docket ID number EPA-HQ-OPP-2006-0815, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy) phenyl]-3-[2,6-diflurobenzoyl]urea, in or on sugarcane, cane at 0.15 parts per million (ppm). This tolerance expires and is revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section

408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Novaluron on Sugarcane and FFDCA Tolerances

The Applicant claims that sugarcane borer populations have recently increased and predator arthropod populations have decreased because of tidal surges as a result of Hurricanes Katrina and Rita in 2005. Additionally, the applicant states that the sugarcane borer developed resistance in some locations to the most commonly used insecticide, because of repeated use. Thus the applicant claims that the registered alternatives will not be adequate to provide control of the sugarcane borer in sugarcane, such that significant economic losses will be suffered. EPA has authorized under FIFRA section 18 the use of novaluron on sugarcane for control of the sugarcane borer in Louisiana. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of novaluron in or on sugarcane. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance expires and is revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sugarcane after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether novaluron meets EPA's registration requirements for use on sugarcane or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of novaluron by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for novaluron, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

Consistent with section 408(b)(2)(D) of the 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 novaluron and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of novaluron in or on sugarcane, cane at 0.15 parts per million (ppm). EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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. Specific information on the studies received and the nature of the toxic 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.epa.gov/EPA-PEST/2004/June/Day-02/p12316.htm*.

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for novaluron used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 2, 2004 (69 FR 31013) (FRL–7359–2).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.598) for the residues of novaluron in or on the following raw agricultural commodities: Apple, wet pomace at 8.0 ppm; Brassica, head and stem, subgroup 5A at 0.50 ppm; cattle, fat at 11 ppm; cattle, kidney at 1.0 ppm; cattle, liver at 1.0 ppm; cattle, meat at 0.60 ppm; cattle, meat byproducts, except liver and kidney at 0.60 ppm; cotton, gin byproducts at 30 ppm; cotton, undelinted seed at 0.60 ppm; eggs at 0.05 ppm; fruit, pome, group 11 at 2.0 ppm; goat, fat at 11 ppm; goat, kidney at 1.0 ppm; goat, liver at 1.0 ppm; goat, meat at 0.60 ppm; goat, meat byproducts except liver and kidney at 0.60 ppm; hog, fat at 0.05 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 11 ppm; horse, kidney at 1.0 ppm; horse, liver at 1.0 ppm; horse, meat at 0.60 ppm; horse, meat byproducts, except liver and kidney at 0.60 ppm; milk at 1.0 ppm; milk, fat at 20 ppm; poultry, fat at 0.40 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.04 ppm; sheep, fat at 11 ppm; sheep, kidney at 1.0 ppm; sheep, liver at 1.0 ppm; sheep, meat at 0.60 ppm; sheep, meat byproducts, except liver and kidney at 0.60 ppm, and vegetables, tuberous and corn, subgroup 1C at 0.05 ppm. Risk assessments were conducted by EPA to assess dietary exposures from novaluron in food as follows:

i. *Acute exposure.* Acute dietary 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 one 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 this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% crops treated for all commodities; average field trial residues; empirical processing factors for apple juice (translated to pear juice); and DEEM™ (ver 7.76) default processing factors for the remaining processed commodities. Furthermore, anticipated residues (ARs) were calculated for meat and milk commodities and the recommended tolerances were used for poultry commodities (partially refined, Tier II analysis).

iii. *Cancer.* A cancer dietary exposure assessment was not conducted because novaluron is classified as ''not likely to be carcinogenic to humans.''

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for novaluron in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of novaluron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov.oppefed1/models/water/index.htm.*

The Agency uses the First Index Reservoir Screening Tool (FIRST) and the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will generally use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

The highest concentrations of novaluron residues in surface water and groundwater are associated with the use on apple (0.96 lb active ingredient/Acre, the highest registered/proposed use rate). The novaluron application scenario associated with apples is higher than the application scenario associated with sugarcane; therefore, the apple data were used for modeling. In drinking water, EPA concluded that the parent compound and degradates chlorophenyl urea, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]urea and chloroaniline, 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline are the residues of concern for risk assessment purposes. (Tier 2 PRZM/EXAMS) modeling was used to estimate drinking water concentrations for surface water for novaluron *per se*. The estimated drinking water concentration (EDWC: 1-in-10 year annual mean) for novaluron *per se* is 1.8 micrograms/Liter (µg/L) (parts per billion (ppb)). For groundwater, the SCI-GROW model was used to predict a groundwater concentration for novaluron. The EDWC for novaluron per se is 5.5×10^{-3} µg/L in drinking water from shallow groundwater sources.

A Tier I drinking water analysis was performed using the FQPA FIRST model to obtain surface water estimates for the chlorophenyl urea and chloroaniline degradates. For surface water, the annual average EDWC for chlorophenyl urea is 0.86 µg/L(ppb) and the annual average EDWC for chloroaniline is 2.6 µg/L(ppb). The SCI-GROW model was

used to predict groundwater concentrations. The predicted ground water EDWC for chlorophenyl urea is 4.5×10^{-3} µg/L, and for chloroaniline the EDWC is 9.0×10^{-3} µg/L. These EDWC values are meant to represent upper-bound estimates of the concentrations that might be found in surface water and groundwater based upon novaluron uses. Of the EDWC values for the three different compounds (novaluron *per se*, and its two degradates, chlorophenyl urea and chloroaniline), the chronic estimate for chloroaniline is the highest (100% conversion from parent to aniline was assumed). This is consistent with the expected degradation pattern for novaluron, so the EDWC value for chloroaniline (2.6 ppb) was used to assess chronic aggregate risk, since it was the highest estimate derived and would represent the most conservative exposure scenario. For chronic dietary risk assessment, the annual average concentration of 2.6 ppb was directly entered into the dietary exposure model (DEEM-FCID™). Since an acute dietary risk assessment was not needed, EECs of novaluron for acute exposures to surface water and ground water were not used.

3. *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 use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to novaluron and 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 not assumed that novaluron has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold 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 that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to novaluron in developmental toxicity studies. There is no quantitative or qualitative evidence of increased susceptibility to novaluron following prenatal/postnatal exposure in a 2-generation reproduction study. EPA determined that the 10X SF to protect infants and children should be reduced to 1X because of the following reasons:

- There is no concern for developmental neurotoxicity resulting from exposure to novaluron. A developmental neurotoxicity study (DNT) study is not required.
- The toxicological database is complete for FQPA assessment.
- Dietary assessments are estimated based on data that reasonably accounts for potential exposures. The chronic dietary food exposure assessment uses the conservative assumption that 100% of the crops are treated for all commodities.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- There are no proposed or existing uses for novaluron which result in residential exposure.

D. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against EDWCs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EDWCs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to novaluron in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of novaluron on drinking water as a part of the aggregate risk assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surfacewater and groundwater EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water

consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk*. 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, 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 exposure to novaluron from food and drinking water contributions will utilize 20% of the cPAD for the U.S. population, 72% of the cPAD for children 1 to 2 years old and 34% of the cPAD for infants less than 1 year old. There are no residential uses for novaluron that result in chronic residential exposure to novaluron. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short- and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be background exposure levels.) Novaluron is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed and do not exceed the Agency's levels of concern.

4. *Aggregate cancer risk for U.S. population*. Novaluron is classified as ''not likely to be carcinogenic to humans'' based on the lack of evidence for carcinogenicity in mice and rats. Therefore, 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, nor to infants and children from aggregate exposure to novaluron residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits for novaluron, so harmonization is not an issue.

VI. Conclusion

Therefore, the tolerance is established for residues of novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-[2,6-diflurobenzoyl]urea, in or on sugarcane, cane at 0.15 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175.

Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: October 12, 2006.

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 adding text to paragraph (b) to read as follows:

§ 180.598 Novaluron; tolerances for residues.

* * * * *

(b) Section 18 emergency exemptions. A time-limited tolerance is established for residues of the fungicide novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy) phenyl]-3-[2,6-diflurobenzoyl]urea in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Sugarcane, cane	0.15	12/31/09

* * * * *

[FR Doc. E6–17566 Filed 10–19–06; 8:45 am]

BILLING CODE 6560–50–S

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Part 2554

RIN 3045–AA42

Program Fraud Civil Remedies Act

AGENCY: Corporation for National and Community Service.

ACTION: Final rule.

SUMMARY: This final rule implements the Program Fraud Civil Remedies Act of 1986 (Act), which authorizes the Corporation for National and Community Service (Corporation) and certain other Federal agencies to impose, through administrative adjudication, civil penalties and assessments against any person who makes, submits, or presents a false, fictitious, or fraudulent claim or written statement to the agency. The regulations establish the procedures the Corporation will follow in implementing the provisions of the Act and specifies the hearing and appeal rights of persons subject to penalties and assessments under the Act. They also designate the Corporation's Chief Financial Officer to act on behalf of the Chief Executive Officer in carrying out certain duties and responsibilities under the regulations.

DATES: *Effective Date:* These regulations are effective November 20, 2006.

FOR FURTHER INFORMATION CONTACT: Irshad Abdal-Haqq, Office of the General Counsel, Corporation for National and Community Service, 1201 New York Ave. NW., Room 10600, Washington, DC 20525, Telephone: 202–606–6675.

SUPPLEMENTARY INFORMATION:

Background

In October 1986, Congress enacted the Program Fraud Civil Remedies Act, Public Law No. 99–509 (codified at 31 U.S.C. 3801–3812), to establish an administrative remedy against any person who makes a false claim or written statement to any of certain Federal agencies. In brief, it requires the affected Federal agencies to follow certain procedures in recovering penalties (up to $5,000 per claim) and assessments (up to double the amount falsely claimed) against persons who file false claims or statements for which the liability is $150,000 or less. When the Act was enacted, the Corporation for National and Community Service did not exist, and the Act did not apply to the Corporation's predecessor agency, ACTION. However, that Act has since become applicable to the Corporation as a result of amendments to the Inspector General Act, Public Law 103–82, September 21, 1993. Those amendments, inter alia, added the Corporation for National and Community Service as an ''establishment'' under the Inspector General Act and, by doing so, operated to bring the Corporation within the provisions of the Program Fraud Civil Remedies Act.

The Act requires each affected agency to promulgate rules and regulations necessary to implement its provisions. Following the Act's enactment, at the request of the President's Council on Integrity and Efficiency (PCIE) an interagency task force was established under the leadership of the Department of Health and Human Services to develop model regulations for implementation of the Act by all affected agencies. This action was in keeping with the stated desire of the Senate Governmental Affairs Committee that ''the regulations would be substantially uniform throughout the government'' (S. Rep. No. 99–212, 99th Cong., 1st Sess. 12 (1985). Upon their completion, the PCIE recommended adoption of the model rules by all affected agencies.

It is the policy of the Corporation to use a plain language style when promulgating regulations, and we have done so in this document without making substantive changes to the PCIE model regulations. For the sake of consistency, we relied, to the extent practicable, on plain language regulations issued by the Small Business Administration in 1996. See 61 FR 2691, January 29, 1996.

A more detailed discussion of the PCIE's model regulations is found in the promulgations of several of the agencies that adopted them earlier, including those of the Departments of Justice (53 FR 4034; February 11, 1988 and 53 FR 11645; April 8, 1988); Health and Human Services (52 FR 27423; July 21, 1987 and 53 FR 11656, April 8, 1988); and Transportation (52 FR 36968; October 2, 1987 and 53 FR 880, January 14, 1988). Anyone desiring further explanation of the model rules is referred to the cited references.

The Corporation published a proposed rule with request for comment in the **Federal Register** on February 1, 2006 (71 FR 5211). Only one comment was received. It expressed general support for the rule as written without any amendments. The commenter believes the rule holds individuals accountable for fraudulent activity and, as such, improves government operations. The commenter also believes the rule's penalty provisions