

**XII. 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: April 17, 2009.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

Inert ingredients	Limits	Uses
* * *	*	*
Morpholine 4-C <sub>6-12</sub> Acyl Derivatives (CAS Reg. No. 887947-29-7)	*	As a solvent
* * *	*	*

[FR Doc. E9-10071 Filed 5-5-09; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0166; FRL-8409-8]

**Novaluron; Pesticide Tolerances for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of novaluron in or on strawberry. 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 strawberries. This regulation establishes a maximum permissible level for residues of novaluron in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2011.

**DATES:** This regulation is effective May 6, 2009. Objections and requests for hearings must be received on or before July 6, 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-2009-0166. All documents in the docket are listed in the docket index available in <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:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; e-mail address: [ertman.andrew@epa.gov](mailto:ertman.andrew@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 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 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (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. 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-2009-0166 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 July 6, 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 your copies, identified by docket ID number EPA-HQ-OPP-2009-0166, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance 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 strawberries at 0.50 parts per million (ppm). This time-limited tolerance expires and is revoked on December 31, 2011. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the CFR.

Section 408(l)(6) of 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 time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of 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 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. . . ."

Section 18 of 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." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## III. Emergency Exemption for Novaluron on Strawberries and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services (FDACS) requested the use of novaluron through an emergency exemption to control sap beetles on strawberries. According to the FDACS, sap beetles are a zero tolerance pest. The presence of larvae in a ripe strawberry can lead to the rejection of the entire shipment. The FDACS stated that even with the currently available insecticides this pest is not adequately controlled as growers have experienced up to 25 percent yield loss due to load rejection. After having reviewed the submission, EPA determined that emergency conditions exist for this State, and that the criteria for an emergency exemption are met. EPA has authorized under FIFRA section 18 the use of novaluron on strawberries for control of sap beetles in Florida.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of novaluron in or on strawberries. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of 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 FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2011, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on strawberries after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited 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 time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether novaluron meets FIFRA's registration requirements for use on strawberries or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision 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 persons in any State other than Florida to use this pesticide on this crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. 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

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 the factors specified in FFDC section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for residues of novaluron on strawberries at 0.50 ppm. EPA’s assessment of exposures and risks associated with establishing time-limited tolerances follows.

#### A. 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 no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) 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 *Novaluron; Human Health Risk Assessment for the Proposed Use in/on Strawberry*, pages 9–10 in docket ID number EPA–HQ–OPP–2009–0166.

#### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to novaluron, EPA considered exposure under the time-limited tolerances established by this action 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.* No acute 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 Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA incorporated anticipated residues (average field trial residues) for some commodities, including strawberries; empirical processing factors for apple juice (translated to pear juice), tomato puree and tomato paste; and Dietary Exposure Evaluation Model (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 FFDC section 408(b)(2)(E) of FFDC 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 FFDC 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 FFDC section 408(b)(2)(E) and authorized under FFDC 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 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(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 SF 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 F<sub>1</sub> 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 considerations in this Unit, 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 neurotoxic 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 PCT and tolerance-level or anticipated residues derived from reliable residue field trials. EPA made conservative (protective) assumptions in the ground water 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.

### D. 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, therefore, 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 76% of the cPAD for children 1–2 years old, the population group receiving the greatest

exposure. There are no residential uses for novaluron.

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 non-dietary, non-occupational 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.* Novaluron has been classified as “not likely to be carcinogenic to humans” and therefore 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.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodologies (a gas chromatography/electron-capture detection (GC/ECD) method; and a high pressure liquid chromatography/ultraviolet detection (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

There are no CODEX residue limits for residues of novaluron on strawberry.

## VI. Conclusion

Therefore, a time-limited tolerance is 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 strawberry at 0.50 ppm. This tolerance expires and is revoked on December 31, 2011.

## VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under sections 408(e) and 408(l)(6) 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 in accordance with sections 408(e) and 408(l)(6) 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).

## VIII. 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: April 28, 2009.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

### PART 180—[AMENDED]

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

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

■ 2. Section 180.598 is amended by revising paragraph (b) to read as follows:

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

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table 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

specified agricultural commodities, resulting from use of the pesticide

pursuant to FFIFRA section 18 emergency exemptions. The tolerances

expire and are revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Strawberry .....	0.50	12/31/11

\* \* \* \* \*

[FR Doc. E9-10499 Filed 5-5-09; 8:45 am]

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**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 64**

[WC Docket No. 04-36, CG Docket No. 03-123, WT Docket No. 96-198 and CC Docket No. 92-105; DA 09-749]

**IP-Enabled Services; Implementation of Sections 255 and 251(a)(2) of the Communications Act of 1934, as Enacted by the Telecommunications Act of 1996: Access to Telecommunications Service, Telecommunications Equipment and Customer Premises Equipment by Persons With Disabilities; Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; extension of waiver.

**SUMMARY:** In this document, the Commission, via the Consumer and Governmental Affairs Bureau, extends the limited waiver granted in the *Implementation of Sections 255 and 251(a)(2) of the Communications Act of 1934, as Enacted by the Telecommunications Act of 1996: Access to Telecommunications Service, Telecommunications Equipment and Customer Premises Equipment by Persons with Disabilities; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities*, Order (2008 TRS 711 Waiver Order) of the requirement that traditional telecommunications relay service (TRS) providers (those providing relay service via the public switched telephone network and a text telephone (TTY)) must automatically and immediately call an appropriate Public Safety Answering Point (PSAP) when receiving an emergency 711-dialed call placed by an interconnected voice over Internet Protocol (VoIP) user. In taking this action, the Commission grants, to the extent provided herein, the petition

for extension of waiver filed by AT&T Inc. (AT&T) and Sprint Nextel Corporation (Sprint) with respect to traditional TRS providers' duty to automatically and immediately route emergency 711 calls that originate on the network of an interconnected VoIP provider.

**DATES:** Effective on April 1, 2009. Traditional TRS providers are granted a waiver until June 29, 2009.

**FOR FURTHER INFORMATION CONTACT:** Lisa Boehley, Consumer and Governmental Affairs Bureau at (202) 418-7395 (voice), or e-mail: [Lisa.Boehley@fcc.gov](mailto:Lisa.Boehley@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's document DA 09-749, adopted and released April 1, 2009. This document also contains a separate document seeking comment on issues raised by the petition for extension of waiver filed by AT&T and Sprint. The full text of this document and copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. This document and copies of subsequently filed documents in this matter may also be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554. Customers may contact the Commission's duplicating contractor at their Web site: <http://www.bcpweb.com> or call 1-800-378-3160. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY). This document can also be downloaded in Word or Portable Document Format (PDF) at: <http://www.fcc.gov/cgb/dro>.

**Synopsis**

On June 15, 2007, the Commission released the Report and Order (*VoIP TRS Order*), published at 72 FR 43546, August 6, 2007, WC Docket No. 04-36, CG Docket No. 03-123, WT Docket No. 96-198 and CC Docket No. 92-105, FCC 07-110. In the *VoIP TRS Order*, the

Commission extended its pre-existing TRS rules to interconnected VoIP providers, including the duty to offer 711 abbreviated dialing access to TRS. The *VoIP TRS Order* required interconnected VoIP providers to offer 711 abbreviated dialing "to ensure that TRS calls can be made from any telephone, anywhere in the United States, and that such calls will be properly routed to the appropriate relay center."

In the Order and Public Notice Seeking Comment (*October 2007 Order and Notice*), released on October 9, 2007, published at 72 FR 61813, November 1, 2007, and 72 FR 61882, November 1, 2007, WC Docket No. 04-36, CG Docket No. 03-123, WT Docket No. 96-198 and CC Docket No. 92-105, DA 07-4178, the Commission clarified the 711 abbreviated dialing requirement adopted in the *VoIP TRS Order* and granted interconnected VoIP providers a six-month waiver of the requirement to route the inbound leg of a 711-dialed call to an "appropriate TRS provider," as defined by the Commission. The Commission also determined that the geographic location identification challenges associated with interconnected VoIP-originated 711 calls rendered traditional TRS providers unable to consistently identify the "appropriate" PSAP to which to route such calls. On this basis, the Commission found good cause to grant traditional TRS providers a six-month waiver of the obligation set forth in § 64.604(a)(4) of its rules to automatically and immediately route the outbound leg of an interconnected VoIP-originated emergency 711 call to an "appropriate" PSAP.

In the *2008 TRS 711 Waiver Order*, released on April 4, 2008, published at 73 FR 28057, May 15, 2008, WC Docket No. 04-36, CG Docket No. 03-123, WT Docket No. 96-198 and CC Docket No. 92-105, DA 07-4178, the Commission granted interconnected VoIP providers an extension of time, until March 31, 2009, to route 711-dialed calls to an appropriate relay center, in the context of 711-dialed calls in which the calling party is using a non-geographically relevant telephone number or a nomadic interconnected VoIP service. The Commission also granted traditional TRS providers an extension of time,