

| Commodity | Parts per million | Expiration/revocation date |
|-------------------------|-------------------|----------------------------|
| Beet, sugar, tops | 0.02 | 12/31/09 |

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the insecticide clothianidin, including its metabolites and degradates. Compliance with the tolerance levels specified below is to be determined by measuring only clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities when present therein as a result of the application of clothianidin to crops listed in paragraph (a) of this section:

| Commodity | Parts per million |
|---|-------------------|
| Animal feed, nongrass, group 18 | 0.02 |
| Grass, forage, fodder and hay, group 17 | 0.02 |
| Soybean, forage | 0.02 |
| Soybean, hay | 0.02 |

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0769; FRL-8799-6]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on bushberry subgroup 13-07B; Brassica, leafy greens, subgroup 5B; turnip, greens; fruit, stone, group 12, except cherry; cherry; and plum, prune, dried. This regulation additionally revises an existing tolerance in or on egg and revises terminology for an existing tolerance. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 9, 2009. Objections and requests for hearings must be received on or before February 8, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0769. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Test Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left side navigation menu.

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-2008-0769 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 8, 2010.

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-2008-0769, 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 December 3, 2008 (73 FR 73640) (FRL-8390-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8E7425 and PP 8E7426) by IR-4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petitions requested that 40 CFR 180.598 be amended by establishing tolerances for residues of the insecticide novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide, in or on bushberry, subgroup 13-07B at 7 parts per million (ppm) (PP 8E7425); fruit, stone, group 12 at 8 ppm (PP 8E7426); Brassica, leafy greens, subgroup 5B at 25 ppm (PP 8E7426); and turnip, greens at 25 ppm (PP 8E7426). PP 8E7426 additionally requested to increase the existing tolerance for residues of novaluron in or on egg from 0.05 ppm to 0.07 ppm; however, the petition number associated with this request was incorrectly reported. The correct petition number for the request to increase the existing egg tolerance is PP 9F7630. The notice referenced summaries of the petitions prepared on behalf of IR-4 by Makhteshim-Agan of North America, Inc., the registrant, which are available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance on stone fruit and has determined that individual tolerances in or on cherry; and plum, prune, dried are necessary. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of novaluron on bushberry subgroup 13-07B at 7.0 ppm; Brassica, leafy greens, subgroup 5B at 25 ppm; turnip, greens at 25 ppm; fruit, stone, group 12, except cherry at 1.9 ppm; cherry at 8.0 ppm; plum, prune, dried at 2.6 ppm; and egg at 0.07 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 RBCs (or erythrocytes) associated with increased erythropoiesis. Increased spleen weights and/or hemosiderosis in the spleen were considered to be due to enhanced removal of damaged erythrocytes and not to an immunotoxic effect.

There was no maternal or developmental toxicity seen in the rat and rabbit developmental toxicity studies up to the limit doses. In the 2-generation reproductive toxicity study in rats, both maternal and offspring toxicity were evidenced by enlargement of the spleen. Reproductive toxicity (decreases in epididymal sperm counts and increased age at preputial separation in the F₁ generation) was observed only in males.

Signs of neurotoxicity were seen in the rat acute neurotoxicity study at the limit dose, including clinical signs (piloerection, fast/irregular breathing), functional observation battery (FOB)

parameters (head swaying, abnormal gait) and neuropathology (sciatic and tibial nerve degeneration). No signs of neurotoxicity or neuropathology were observed in the subchronic neurotoxicity study in rats or in any other subchronic or chronic toxicity study in rats, mice or dogs. Therefore, there is no concern for neurotoxicity resulting from exposure to novaluron.

There was no evidence of carcinogenic potential in either the rat or mouse carcinogenicity studies and no evidence of mutagenic activity in the submitted mutagenicity studies, including a bacterial (*Salmonella, E. coli*) reverse mutation assay, an *in vitro* mammalian chromosomal aberration assay, an *in vivo* mouse bone-marrow micronucleus assay and a bacterial DNA damage or repair assay. Based on the results of these studies, EPA has classified novaluron as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by novaluron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Novaluron: Human-Health Risk Assessment for Proposed Section 3 Uses on Bushberry Crop Subgroup 13-07B; Brassica, Leafy Greens, Crop Subgroup 5B; Turnip, Greens; and Fruit, Stone, Crop Group 12," pages 28-31 in docket ID number EPA-HQ-OPP-2008-0769.

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 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-, intermediate-, 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 Proposed Section 3 Uses on Bushberry Crop Subgroup 13-07B; Brassica, Leafy Greens, Crop Subgroup 5B; Turnip, Greens; and Fruit, Stone, Crop Group 12," pages 13-14 in docket ID number EPA-HQ-OPP-2008-0769.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to novaluron, EPA considered exposure under the petitioned-for tolerances as well as all existing novaluron tolerances in 40 CFR 180.598. EPA assessed dietary exposures from novaluron in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for novaluron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA incorporated anticipated residues from average field trial residues for pome fruit, sugarcane, bushberries, Brassica leafy greens, stone fruit and greenhouse tomatoes; empirical processing factors for apple juice (translated to pear and stone fruit juice), tomato paste and purée, and dried

plums; and DEEM 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 lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, EPA has classified novaluron as "not likely to be carcinogenic to humans." Therefore, a quantitative exposure assessment to evaluate cancer risk 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>.

The following models were used to assess residues of concern in drinking water: The Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) for parent novaluron in surface water; the First Index Reservoir Screening Tool (FIRST) for chlorophenyl urea and chloroaniline degradates in surface water; and the Screening Concentration in Ground Water (SCI-GROW) model for novaluron, chlorophenyl urea and chloroaniline in ground water. The

estimated drinking water concentrations (EDWCs) of novaluron, chlorophenyl urea and chloroaniline for chronic exposures for non-cancer assessments are estimated to be 0.76 parts per billion (ppb), 0.89 ppb and 2.6 ppb, respectively, for surface water and 0.0056 ppb, 0.0045 ppb and 0.0090 ppb, respectively, for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The highest drinking water concentrations were estimated for surface water. Of the three EDWC values for surface water, the chronic EDWC for the terminal metabolite, chloroaniline, is the highest (assuming 100% molar conversion from parent to aniline). This is consistent with the expected degradation pattern for novaluron. Therefore, for chronic dietary risk assessment, the water concentration value for chloroaniline of 2.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Novaluron is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found novaluron to share a common mechanism of toxicity with any other substances, and novaluron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that novaluron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the

case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for novaluron includes rat and rabbit prenatal developmental toxicity studies and a 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility following *in utero* exposure to rats or rabbits in the developmental toxicity studies and no evidence of increased quantitative or qualitative susceptibility of offspring in the reproduction study. Neither maternal nor developmental toxicity was seen in the developmental studies up to the limit doses. In the reproduction study, offspring and parental toxicity (increased absolute and relative spleen weights) were similar and occurred at the same dose; additionally, reproductive effects (decreases in epididymal sperm counts and increased age at preputial separation in the F₁ generation) occurred at a higher dose than that which resulted in parental toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for novaluron is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Test Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. Although effects were seen in the spleen in two studies, as explained in Unit III.A., EPA has concluded that novaluron does not directly target the immune system and the Agency does not believe that conducting a functional immunotoxicity study will result in a NOAEL lower than the regulatory dose for risk assessment; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There were signs of neurotoxicity in the acute neurotoxicity study in rats, including clinical signs (piloerection, fast/irregular breathing), FOB parameters (head swaying, abnormal gait), and neuropathology (sciatic and tibial nerve degeneration). However, the signs observed were not severe, were seen only at the limit dose (2,000 mg/kg/day) and were not reproducible. No signs of neurotoxicity or neuropathology were observed in the subchronic neurotoxicity study in rats at doses up to 1,752 mg/kg/day in males and 2,000 mg/kg/day in females or in any other subchronic or chronic toxicity study in rats, mice or dogs, including the developmental and reproduction studies. Therefore, novaluron does not appear to be a neurotoxicant, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that novaluron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT 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-, intermediate-, 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 83% 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- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Novaluron is not registered for any use patterns that would result in residential exposure. Therefore, the short- and intermediate-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. *Aggregate cancer risk for U.S. population.* 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; therefore, novaluron is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The following adequate enforcement methodologies are available to enforce the tolerance expression: A gas chromatography/electron-capture detection (GC/ECD) method and a high-performance liquid chromatography/ultraviolet (HPLC/UV) method. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

No Codex, Canadian or Mexican maximum residue limits (MRLs) have been established for novaluron on bushberries; Brassica, leafy greens; turnip greens; or stone fruit. Canada has reviewed the use of novaluron on Brassica, leafy greens and stone fruit

(including cherry and plum, prune, dried). Canadian and U.S. recommendations have been harmonized and MRLs for Brassica, leafy greens, subgroup 5B at 7.0 ppm; stone fruit, group 12, except cherry at 1.9 ppm; cherry at 8.0 ppm; and plum, prune, dried at 2.6 ppm are expected to be established in Canada.

C. Revisions to Petitioned-For Tolerances

Based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*, EPA revised the proposed tolerance on fruit, stone, group 12 (excluding cherry; and plum, prune, dried) from 8.0 ppm to 1.9 ppm and determined that individual tolerances on cherry at 8.0 ppm and plum, prune, dried at 2.6 ppm are necessary. For peaches, fresh plums and cherries (the representative commodities for fruit, stone, group 12) the tolerance spreadsheet recommends tolerances of 1.8 ppm, 1.9 ppm, and 8.0 ppm, respectively. For plum, prune, dried, the tolerance spreadsheet recommends a tolerance of 2.6 ppm. Therefore, tolerances of novaluron in or on fruit, stone, group 12, except cherry at 1.9 ppm; cherry at 8.0 ppm; and plum, prune, dried at 2.6 ppm are appropriate. EPA has also revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of novaluron not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

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 bushberry subgroup 13-07B at 7.0 ppm; Brassica, leafy greens, subgroup 5B at 25 ppm; turnip, greens at 25 ppm; fruit, stone, group 12, except cherry at 1.9 ppm; cherry at 8.0 ppm; plum, prune, dried at 2.6 ppm; and egg at 0.07 ppm. EPA also revised the commodity definition for vegetables, tuberous and corn, subgroup 1C to vegetable, tuberous and corm, subgroup 1C to reflect the correct commodity definition.

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 13, 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. Section 180.598 is amended by:

- Revising the introductory text in paragraph (a);
- Revising the existing entries for "Egg" and "Vegetables, tuberous and corn, subgroup 1C" in the table in paragraph (a) and alphabetically adding "Brassica, leafy greens, subgroup 5B"; "Bushberry subgroup 13-07B"; "Cherry"; "Fruit, stone, group 12, except cherry"; "Plum, prune, dried"; and "Turnip, greens" to the table in paragraph (a); and
- Revising the introductory text in paragraph (b).

The amendments read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide novaluron, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels specified in the following table is to be determined by

measuring only 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 |
|---|-------------------|
| Brassica, leafy greens, subgroup 5B | 25 |
| Bushberry subgroup 13-07B | 7.0 |
| Cherry | 8.0 |
| Egg | 0.07 |
| Fruit, stone, group 12, except cherry | 1.9 |
| Plum, prune, dried | 2.6 |
| Turnip, greens | 25 |
| Vegetable, tuberous and corm, subgroup 1C | 0.05 |

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide novaluron, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified in the following table is to be determined by measuring only novaluron, (N-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide). These tolerances will expire and are revoked on the dates specified in the following table:

| Commodity | Expiration Date |
|---|-----------------|
| Brassica, leafy greens, subgroup 5B | 12/31/2010 |
| Bushberry subgroup 13-07B | 12/31/2010 |
| Cherry | 12/31/2010 |
| Egg | 12/31/2010 |
| Fruit, stone, group 12, except cherry | 12/31/2010 |
| Plum, prune, dried | 12/31/2010 |
| Turnip, greens | 12/31/2010 |
| Vegetable, tuberous and corm, subgroup 1C | 12/31/2010 |

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FEDERAL MARITIME COMMISSION

46 CFR Part 535

[Docket No. 09-02]

RIN 3072-AC 35

Repeal of Marine Terminal Agreement Exemption

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission repeals the marine terminal agreements exemption, which exempted

such agreements from the Shipping Act's 45-day statutory waiting period, and amends the Commission's regulations to transfer an existing definition of the marine terminal conference agreement to another section. This rule also corrects a typographical error.

DATES: Effective December 10, 2009.

FOR FURTHER INFORMATION CONTACT: Peter J. King, General Counsel, Federal Maritime Commission, 800 North Capitol Street, NW., Room 1018, Washington, DC 20573-0001, generalcounsel@fmc.gov.

SUPPLEMENTARY INFORMATION: By Notice of Proposed Rulemaking (NPR) published in the **Federal Register** on July 2, 2009, 74 FR 31666, the Commission proposed to repeal 46 CFR 535.308, which exempts marine terminal agreements from the 45-day waiting period requirement of the Shipping Act. The NPR addresses the Commission's findings and concerns that agreements filed under section 535.308 could cause anticompetitive consequences that the Commission deemed unlikely when it first adopted the exemption in 1987.

The Commission invited comments on the NPR. The comments period was later extended to September 8, 2009. 74 FR 41831, Aug. 19, 2009.

Comments

Three comments were filed with the Commission. Two comments support repeal of section 535.308 exemption as proposed in the NPR, and one comment opposes the repeal.

The National Customs Brokers and Forwarders Association of America (NCBFAA) is the national trade association representing the interests of freight forwarders, NVOCCs, and customs brokers in the ocean shipping industry. NCBFAA notes that under section 535.308, exempt marine terminal agreements (MTAs) are immunized from the antitrust laws immediately upon filing with the Commission. NCBFAA states that agreements between terminal operators have evolved in their nature from simple landlord-tenant agreements, and that some marine terminal operators have begun using the exempt MTAs to "collectively adopt policies, procedures and regulations" affecting the shipping industry. Due to the exemption, parties adversely affected by exempt MTAs, as well as the Commission itself, are deprived of opportunities to consider the adverse consequences of any exempt MTAs before such agreements become effective. Although NCBFAA does not challenge continued antitrust immunity

under the Shipping Act, it believes that MTAs that could have anticompetitive consequences should no longer be exempted from the 45-day waiting period established by the Shipping Act, 46 U.S.C. 40304.

The National Industrial Transportation League (NITL) is a national association that represents approximately 700 member companies that tender goods to carriers for transportation in interstate and international commerce or that arrange or perform transportation services. NITL's membership includes large multinational and national corporations as well as small and medium-sized companies. NITL states that MTAs have an impact on the shipment of its members because many of them are U.S. importers and exporters. NITL notes that agreement of terminal operators have become "more complex and broader in scope." This change, NITL states, has created a legitimate concern as to whether MTAs should be granted antitrust immunity immediately upon filing with the Commission. NITL supports repeal of the exemption for MTAs from the 45-day waiting period.

The Ports of Los Angeles and Long Beach (the Ports) submitted a comment objecting to the elimination of the 45-day waiting period exemption for MTAs. The Ports allege that the Commission's efforts to eliminate the waiting period exemption arise largely out of the efforts to delay and block the implementation of agreements the Ports filed in connection with their environmental programs. The Ports state that the MTA exemption does not impede Commission oversight. The Ports argue that elimination of the section 535.308 exemption will cause them "to interrupt and delay operational matters" to accommodate the 45-day waiting period.

The Ports also argue that the Commission's marine terminal operator agreement rules are unclear and provide no guidance regarding the degree of specificity and detail required for filed agreements. The Ports allege that this confusion stems from the Commission's elimination in Docket No. 03-15 of the exemption for "routine operational and administrative matters," which were previously exempted from filing under 46 CFR 535.407(c) (2003). The Ports assert that, in lieu of the section 535.407(c) exemption, the Commission provided in section 535.408 a list of exemptions that are specific to vessel-operating common carriers and do not address marine terminal operators at all. The Ports claim that repeal of the section 308 exemption will cause long delays for every "trivial" amendment to