

(i) Sulfur dioxide (SO₂) in all PM_{2.5} nonattainment and maintenance areas,
 (ii) Nitrogen oxides in all PM_{2.5} nonattainment and maintenance areas unless both the State and EPA determine that it is not a significant precursor, and
 (iii) Volatile organic compounds (VOC) and ammonia (NH₃) only in PM_{2.5} nonattainment or maintenance areas where either the State or EPA determines that they are significant precursors.

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 ■ 6. Section 93.153 is amended by revising paragraph (b) to read as follows:

§ 93.153 Applicability analysis.

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 (b) For Federal actions not covered by paragraph (a) of this section, a conformity determination is required for each criteria pollutant or precursor where the total of direct and indirect emissions of the criteria pollutant or precursor in a nonattainment or maintenance area caused by a Federal action would equal or exceed any of the rates in paragraphs (b)(1) or (2) of this section.

(1) For purposes of paragraph (b) of this section, the following rates apply in nonattainment areas (NAA's):

	Tons/ year
Ozone (VOC's or NO _x):	
Serious NAA's	50
Severe NAA's	25
Extreme NAA's	10
Other ozone NAA's outside an ozone transport region	100
Other ozone NAA's inside an ozone transport region:	
VOC	50
NO _x	100
Carbon monoxide: All NAA's	100
SO ₂ or NO ₂ : All NAA's	100
PM-10:	
Moderate NAA's	100
Serious NAA's	70
PM _{2.5} :	
Direct emissions	100
SO ₂	100
NO _x (unless determined not to be significant precursors)	100
VOC or ammonia (if determined to be significant precursors)	100
Pb: All NAA's	25

* * * * *
 (2) For purposes of paragraph (b) of this section, the following rates apply in maintenance areas:

	Tons/ year
Ozone (NO _x , SO ₂ or NO ₂): All Maintenance Areas	100
Ozone (VOC's):	

	Tons/ year
Maintenance areas inside an ozone transport region	50
Maintenance areas outside an ozone transport region	100
Carbon monoxide: All Maintenance Areas	100
PM-10: All Maintenance Areas	100
PM _{2.5} :	
Direct emissions	100
SO ₂	100
NO _x (unless determined not to be significant precursors)	100
VOC or ammonia (if determined to be significant precursors)	100
Pb: All Maintenance Areas	25

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0525; FRL-7756-8]

Novaluron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of novaluron in or on brassica, head and stem, subgroup 5A. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 5, 2006. Objections and requests for hearings must be received on or before June 5, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2005-0525. All documents are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: brothers.shaja@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 and Other Related Information?

In addition to using EDOCKET <http://www.epa.gov/edocket/>, you may access

this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of January 18, 2006 (71 FR 2927) (FRL-7756-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E6834) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.598 be amended by establishing a tolerance for residues of the insecticide novaluron, [(N [[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide), in or on brassica, head and stem, subgroup 5A at 0.50 parts per million (ppm). That notice included a summary of the petition prepared by Makhteshim-Agan of North America, Inc., the registrant. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCFA 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 FFDCFA 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 FFDCFA 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. . . .”

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 FFDCFA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCFA, 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, consistent with section 408(b)(2) of FFDCFA, for a tolerance for residues of novaluron on brassica, head and stem, subgroup 5A at 0.50 ppm. EPA’s assessment of exposures and risks associated with establishing the tolerance 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. 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>.

B. Toxicological Endpoints

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).

C. 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; 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.* 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 Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (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 was 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 FFDCFA 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 FFDCFA section 408(b)(2)(E) and authorized under FFDCFA 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>.

Tier 2 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) modeling was performed to estimate drinking water concentrations for surface water for

novaluron *per se*. The scenarios were selected to provide high-end drinking water concentrations for each crop and represent the geographic locations where the specific crops are grown in large quantities.

The most-conservative estimates were obtained for airblast applications to Pennsylvania apples at the maximum annual application rate of 0.96 pound active ingredient/acre (lb a.i./acre), applied three times at 0.32 lb a.i./acre with an interval between applications of 10 days.

For surface water, the 1-in-10 year annual mean estimated drinking water concern (EDWC) for the parent novaluron is 1.8 micrograms/Liter ($\mu\text{g/L}$) (ppb).

A Tier I drinking water analysis was performed for the chlorophenyl urea and chloroaniline degradates. The FQPA Index Reservoir Screening Tool (FIRST) model was used to obtain surface water estimates. As a conservative assumption, the model assumed chlorophenyl urea was directly applied, i.e., as granular, to the field, assuming no spray drift and no foliar interception. The FIRST model estimates a peak and an annual average value based on the Index Reservoir scenario.

For surface water, the annual average EDWC for chlorophenyl urea is 0.86 $\mu\text{g/L}$ (ppb) and the annual average EDWC for chloroaniline is 2.6 $\mu\text{g/L}$ (ppb). Both of these estimates are based upon the maximum application rate in apples.

For ground water, the screening concentration in ground water (SCI-GROW) model was used to predict a ground water concentration for novaluron at the annual application rate of 0.96 lb a.i./acre (i.e., three applications of 0.32 lb a.i./acre). The estimate for the parent novaluron is 5.5×10^{-3} $\mu\text{g/L}$ in drinking water from shallow ground water sources. For the chlorophenyl urea degradate, the predicted ground water concentration is 4.5×10^{-3} $\mu\text{g/L}$, and for the chloroaniline degradate the concentration is 9.0×10^{-3} $\mu\text{g/L}$. These concentrations were estimated with the same assumptions used for surface water modeling, and may be considered as both the peak and annual average upper bound exposures.

These EDWC values are meant to represent upper-bound estimates of the concentrations that might be found in surface water and ground water based upon existing and proposed uses. Of the three EDWC values, chronic estimates for the terminal metabolite, chloroaniline are the highest (100% conversion from parent to aniline was assumed). This is consistent with the expected degradation pattern for

novaluron. Therefore, the EDWC value for the chloroaniline degradate (2.6 ppb) was used to assess chronic aggregate risk.

Based on the FIRST, PRZM/EXAMS, and SCI-GROW models, the estimated environmental concentrations (EECs) of novaluron for acute exposures are estimated to be 1.8 parts per billion (ppb) for novaluron, and 2.6 ppb for the chloroaniline degradate for surface water, respectively. The EECs for chronic exposures are estimated to be 2.6 ppb surface water and 0.009 ppb ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For chronic dietary risk assessment, the annual average concentration of 2.6 ppb was used to access 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 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 FFDCFA 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/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of 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 data base on toxicity and exposure unless EPA determines based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

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% crops 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.

E. 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. The DWLOC values are not regulatory standards for drinking water, but 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 population adjusted dose (PAD)) is available for exposure through drinking water e.g., allowable chronic water exposure milligrams/kilogram/day (mg/kg/day) = chronic PAD - (average food + residential 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 EPA's 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). 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 ground water are less than the calculated DWOCs, EPA can conclude with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposures for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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. When new uses are added, EPA reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate 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 surface water and ground water 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 GSFII 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 plus water will utilize 20% of the cPAD for the U.S. population, 33% of the cPAD for infants < 1 year old, and 71% of the cPAD for children 1-2 years old. There are no residential uses for novaluron. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk/intermediate-term risk.* Short and intermediate-term aggregate exposures take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). 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 do not exceed the Agency's level 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.

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, and to infants and children from aggregate exposure to novaluron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology Gas Chromatography/Electron Capture Detection (GC/EDC) 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 (MRLs) for novaluron.

V. Conclusion

Therefore, the 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 brassica, head and stem, subgroup 5A at 0.50 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2005-0525 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 June 5, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any

evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2005-0525, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account

uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 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 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. 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 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: March 27, 2006.

Losi 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 alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Brassica, head and stem, subgroup 5A	0.50
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2004-0292; FRL-7772-8]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate), expressed as parent compound, in or on bean, succulent, shelled; legume vegetables group, foliage, in crop group 7; mango (import); and papaya (import).

This final rule also increases the tolerances for almond, hulls; pea and bean, dried shelled, except soybean, subgroup 6C; and strawberry. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 5, 2006. Objections and requests for hearings must be received on or before June 5, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2004-0292. All documents in the docket are listed on the regulations.gov website. (EDOCKET, EPA’s electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, e.g., 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 electronically through regulations.gov or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open 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: Tony Kish, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9443; e-mail address: kish.tony@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: