Contaminant	Methodology	Reference (method or page number)							
		EPA [1]	EPA [2]	EPA [3]	EPA [4]	SM [5]	ASTM [6]	USGS [7]	DOE [8]
	Alpha spectrometry.	.....	.....	00–07	p–33	7500–U C (18th, 19th or 20th Ed.)	D3972–97	R–1182–76	U–02
	Laser Phosphorimetry.	.....	.....	.....	.....		D5174–97		

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The procedures shall be done in accordance with the documents listed below. The incorporation by reference of documents 1 through 10 and 13 was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the documents may be obtained from the sources listed below. Information regarding obtaining these documents can be obtained from the Safe Drinking Water Hotline at 800–426–4791. Documents may be inspected at EPA's Drinking Water Docket, EPA West, 1301 Constitution Avenue, NW, Room B135, Washington, DC (Telephone: 202–566–2426); or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

[1] ''Prescribed Procedures for the Measurement of Radioactivity in Drinking Water'', EPA 600/4–80–032, August 1980. Available at the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (Telephone 800–553–6847), PB 80–224744, except Method 200.8, ''Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Revision 5.4, which is published in ''Methods for the Determination of Metals in Environmental Samples—Supplement I,'' EPA 600–R–94–111, May 1994. Available at NTIS, PB95–125472.

[2] ''Interim Radiochemical Methodology for Drinking Water'', EPA 600/4–75–008(revised), March 1976. Available at NTIS, ibid. PB 253258.

[3] ''Radiochemistry Procedures Manual'', EPA 520/5–84–006, December, 1987. Available at NTIS, ibid. PB 84–215581.

[4] ''Radiochemical Analytical Procedures for Analysis of Environmental Samples'', March 1979. Available at NTIS, ibid. EMSL LV 053917.

[5] ''Standard Methods for the Examination of Water and Wastewater'', 13th, 17th, 18th, 19th Editions, or 20th edition, 1971, 1989, 1992, 1995, 1998. Available at American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005. Methods 302, 303, 304, 305 and 306 are only in the 13th edition. Methods 7110B, 7500–Ra B, 7500–Ra C, 7500–Ra D, 7500–U B, 7500–Cs B, 7500–I B, 7500–I C, 7500–I D, 7500–Sr B, 7500–3H B are in the 17th, 18th, 19th and 20th editions. Method 7110 C is in the 18th, 19th and 20th editions. Method 7500–U C Fluorometric Uranium is only in the 17th Edition, and 7500–U C Alpha spectrometry is only in the 18th, 19th and 20th editions. Method 7120 is only in the 19th and 20th editions. Methods 302, 303, 304, 305 and 306 are only in the 13th edition. Method 3125 is only in the 20th edition.

[6] *Annual Book of ASTM Standards*, Vol. 11.01 and 11.02, 1999; ASTM International any year containing the cited version of the method may be used. Copies of these two volumes and the 2003 version of D 5673–03 may be obtained from ASTM International. 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA, 19428–2959.

[7] ''Methods for Determination of Radioactive Substances in Water and Fluvial Sediments'', Chapter A5 in Book 5 of *Techniques of Water-Resources Investigations of the United States Geological Survey*, 1977. Available at U.S. Geological Survey (USGS) Information Services, Box 25286, Federal Center, Denver, CO 80225–0425.

[8] ''EML Procedures Manual'', 28th (1997) or 27th (1990) Editions, Volumes 1 and 2; either edition may be used. In the 27th Edition Method Ra–04 is listed as Ra–05 and Method Ga–01–R is listed as Sect. 4.5.2.3. Available at the Environmental Measurements Laboratory, U.S. Department of Energy (DOE), 376 Hudson Street, New York, NY 10014–3621.

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[12] If uranium (U) is determined by mass, a 0.67 pCi/μg of uranium conversion factor must be used. This conversion factor is based on the 1:1 activity ratio of U–234 and U–238 that is characteristic of naturally occurring uranium.

[13] ''Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Revision 5.4, which is published in ''Methods for the Determination of Metals in Environmental Samples—Supplement I,'' EPA 600–R–94–111, May 1994. Available at NTIS, PB 95–125472.

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[FR Doc. 04–12299 Filed 6–1–04; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0125; FRL–7359–2]

Novaluron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on fruit, pome (group 11), apple, wet pomace; cotton, undelinted seed; cotton, gin byproducts; vegetables, tuberous and corm, subgroup 1C; meat, fat, and meat byproducts of sheep, horse, cattle, goat, hog, and poultry; milk; milk, fat; and eggs. Makhteshim-Agan of North America, Inc. 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 June 2, 2004. Objections and requests for hearings must be received on or before August 2, 2004.

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 ID number OPP–2004–0125. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* 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, 1921 Jefferson Davis Hwy., 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: Daniel C. Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address: *kenny.dan@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 February 25, 2004 (69 FR 8649) (FRL–7344–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F6430) by Makhteshim-Agan of North America, Inc., 551 Fifth Avenue, Suite 1100, New York, NY 10176. 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.

The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the insecticide novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoro-methoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea, in or on fruit, pome (group 11) at 2.0 parts per million (ppm), apple, wet pomace at 8.0 ppm; cotton, undelinted seed at 0.60 ppm; cotton, gin byproducts at 30 ppm; vegetables, tuberous and corm, subgroup 1C at 0.05 ppm; sheep, horse, cattle, and goat, meat at 0.60 ppm; sheep, horse, cattle, and goat, meat byproducts (except liver and kidney) at 0.60 ppm; sheep, horse, cattle, and goat, fat at 11 ppm; sheep, horse, cattle, and goat, liver at 1.0 ppm; sheep, horse, cattle, and goat, kidney at 1.0 ppm; milk at 1.0 ppm; milk, fat at 20 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; hog, fat at 0.05 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.04 ppm; poultry, fat at 0.40 ppm; and eggs at 0.05 ppm.

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. . . .''

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 FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of novaluron on fruit, pome (group 11) at 2.0 ppm, apple, wet pomace at 8.0 ppm; cotton, undelinted seed at 0.60 ppm; cotton, gin byproducts at 30 ppm; vegetables, tuberous and corm, subgroup 1C at 0.05 ppm; sheep, horse, cattle, and goat, meat at 0.60 ppm; sheep, horse, cattle, and goat, meat byproducts (except liver and kidney) at 0.60 ppm; sheep, horse, cattle, and goat, fat at 11 ppm; sheep, horse, cattle, and goat, liver at 1.0 ppm; sheep, horse, cattle, and goat, kidney at 1.0 ppm; milk at 1.0 ppm; milk, fat at 20 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; hog, fat at 0.05 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.04 ppm; poultry, fat at 0.40 ppm; and eggs at 0.05 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. The nature of the toxic effects caused by novaluron are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No	Study Type	Results
870.3200	28–day Dermal toxicity - rat	Systemic NOAEL= 1,000 mg/kg/day; LOAEL= not established Dermal NOAEL= 1,000 mg/kg/day; LOAEL= not established
870.3700	Prenatal Developmental in rodents-rat.	Maternal NOAEL: ≥1,000; LOAEL: not established Developmental NOAEL: ≥ 1,000; LOAEL: not established

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No	Study Type	Results
870.3700	Prenatal developmental in non-rodents-rabbit.	Maternal NOAEL: ≥1,000; LOAEL: not established Developmental NOAEL: ≥ 1,000; LOAEL: not established
870.3800	Reproduction and fertility- rat	Parental NOAEL= Not established; LOAEL (M/F)= 74.2/84.0 mg/kg/day based on increased absolute and relative spleen weights. Offspring NOAEL= Not established; LOAEL (M/F)= 74.2/84.0 mg/kg/day based on increased absolute and relative spleen weights. Reproductive NOAEL (M/F)= 74.2 ≥1009.8 mg/kg/day; LOAEL= 297.5 mg/kg/day based on decreased epididymal sperm counts and increased age of preputial separation in the F_1 generation, reproductive LOAEL for females was not established
870.4100	Chronic toxicity - dog	NOAEL= 10 mg/kg/day LOAEL=100 mg/kg/day based on hematologic changes associated with histopathological changes in liver and spleen
870.4300	Chronic/carcinogenicity-rat	NOAEL (M/F) =1.1/1.4 mg/kg/day LOAEL (M/F)=30.6/39.5 mg/kg/day based on Erythrocyte damage and turnover resulting in a regenerative mild anemia
870.4300	Chronic/carcinogenicity-mouse	NOAEL (M/F)=3.6/4.3 mg/kg/day LOAEL (M/F)=53.4/63.3 mg/kg/day based on increased erythrocyte turnover due to hemoglobin oxidation and resulting in a mild anemia
870.5100	*Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay.	Novaluron, tested up to the limit of solubility (2,500 μg/plate) and the limit dose (5,000 μg/plate), was not cytotoxic with or without S9 activation in four *S. typhimurium* strains and one strain of *E. coli*, and did not induce a genotoxic response in any strain
870.5100	*Salmonella typhimurium* - bacterial reverse gene mutation assay.	Novaluron, tested up to the limit of solubility (3333 μg/plate), was not cytotoxic with or without S9 activation in five *S. typhimurium* strains, and did not induce a genotoxic response in any strain
870.5300	Gene mutation	There was no evidence of biologically significant induction of mutant colonies over background
870.5375	*In vitro* mammalian chromosome aberration test.	Novaluron produced no evidence of clastogenic activity in primary human lymphocytes, in the presence or absence of S9 activation
870.5395	Mammalian erythrocyte micronucleus test in mice.	There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or harvest time
870.5550	Unscheduled DNA Synthesis in HeLa S3 Human Epitheliod cells.	Novaluron was considered not to show any evidence of causing DNA damage to HeLa S3 epithelioid cells in this unscheduled DNA synthesis test for mutagenic potential
870.5500	Mutagenicity-rec assay with *Bacillus subtilis*.	Novaluron was equivocal for bacterial DNA damage in the absence of S9 activation, and negative for bacterial DNA damage in the presence of S9 activation
870.6200	Acute neurotoxicity screening battery- rat.	NOAEL= 650 mg/kg/day; LOAEL=2,000 mg/kg/day based on clinical signs (piloerection, irregular breathing), FOB parameters (increased head swaying, abnormal gait) and neuropathology (sciatic and tibial nerve degeneration).
870.6200	Subchronic neurotoxicity screening battery- rat.	NOAEL (M/F)=≥1,752/≥2,000 mg/kg/day; LOAEL= not established
870.7485	Metabolism-rat	Novaluron exhibited marginal absorption (16–18%), relatively rapid and complete excretion within 48 hours primarily via the feces and to a lesser extent via urine in rat
870.7600	Rat Dermal penetration	Recovery of administered radioactivity was an acceptable 90.19–105.26%. The maximum total absorbed dose (expressed as per cent of administered dose and determined as the sum of radioactivity in excreta, cage wash, untreated skin, fat, blood, and residual carcass) ranged from about 0.5% to 10% of that administered.

M - Male; F - Female

B. Toxicological Endpoints

The dose at which 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 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{6}), or one in ten million (1×10^{7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for novaluron used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR NOVALURON FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary	Not applicable	None	An endpoint of concern attributable to a single dose was not identified. An acute RfD was not established
Chronic dietary (All populations)	NOAEL= 1.1 mg/kg/day UF = 100 Chronic RfD = 0.011 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD÷FQPA SF = 0.011 mg/kg/day	Combined chronic toxicity/carcinogenicity feeding in rat LOAEL = 30.6 mg/kg/day based on erythrocyte damage and turnover resulting in a regenerative anemia
Short-term incidental oral (1–30 days)	NOAEL= 4.38 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day feeding study in rat LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver).
Intermediate-term incidental oral (1– 6 months)	NOAEL= 4.38 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day feeding study in rat LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver)
Short-term dermal (1 to 30 days)	Not applicable	None	No toxicity observed at the limit dose in dermal study and there were no developmental toxicity concerns at the limit-dose; therefore, quantification of short-term dermal risk is not necessary

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR NOVALURON FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Intermediate-term dermal (1 to 6 months)	Oral NOAEL = 4.38 mg/kg/day(dermal-absorption rate = 10%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day feeding study in rat LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver)
Long-term dermal (>6months)	Oral NOAEL= 1.1 mg/kg/day (dermal-absorption rate = 10 %)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Combined chronic toxicity/carcinogenicity feeding in rat LOAEL = 30.6 mg/kg/day based on erythrocyte damage and turnover resulting in a regenerative anemia
Short-term inhalation (1 to 30 days)	Oral NOAEL = 4.38 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day feeding study in rat LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver)
Intermediate-term inhalation (1 to 6 months)	Oral NOAEL = 4.38 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day feeding study in rat LOAEL = 8.64 mg/kg/day based on clinical chemistry (decreased hemoglobin, hematocrit and RBC counts) and histopathology (increased hematopoiesis and hemosiderosis in spleen and liver).
Long-term inhalation (>6 months)	Oral NOAEL= 1.1 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Combined chronic toxicity/carcinogenicity feeding in rat LOAEL = 30.6 mg/kg/day based on erythrocyte damage and turnover resulting in a regenerative anemia
Cancer	Not likely to be carcinogenic to humans		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Currently, no tolerances have been established for the residues of novaluron, in or on any raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from novaluron in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. An endpoint of concern attributable to a single dose of novaluron was not identified. Therefore, an acute dietary risk assessment was not conducted.

ii. *Chronic exposure*. In conducting the chronic dietary risk 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 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: The chronic analysis assumed 100% crop treated for all commodities; incorporated 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. Anticipated residues were calculated for meat and milk commodities and recommended tolerances were used for poultry commodities.

iii. *Cancer*. Novaluron is classified as ''not likely to be carcinogenic to humans'' based on the lack of evidence for carcinogenicity in mice and rats. Therefore, a quantitative cancer risk assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) 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 chemicals that have been measured in food. If EPA relies on such information, EPA must 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. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues 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. Novaluron may reach surface water or ground water via the parent compound or via its chlorophenyl urea and chloroaniline degradates. Therefore, concentrations of novaluron and its chlorophenyl urea and chloroaniline degradates in surface water and ground water were estimated by using modeling.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and screening concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier I model) before using PRZM/EXAMS (a Tier II model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin. Tier II Pesticide Root Zone Model/ Exposure Analysis Modeling System (PRZM/EXAMS) modeling was performed to estimate drinking water concentrations for novaluron (parent) in surface water.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/ EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier I model) before using PRZM/EXAMS (a Tier II model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/ EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin. The FIRST model was used to obtain surface water estimates for the degradate chlorophenyl urea and chloroaniline. The estimated drinking water concentration 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 estimated drinking water concentration 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 estimated drinking water concentration value for chloroaniline was used to assess chronic aggregate risk.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to novaluron they are further discussed in the aggregate risk sections in this Unit.

Based on the PRZM/EXAMS, FIRST and SCI-GROW models, the EECs of novaluron for chronic exposures are estimated to be 2.61 parts per billion (ppb) for surface water and 0.009 ppb for ground water. Since an acute dietary risk assessment was not needed, EECs of novaluron for acute exposures to surface water and ground water were not used.

3. *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 FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to novaluron and any other substances and novaluron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that novaluron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site 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 are no residual uncertainties for pre-/post-natal toxicity. 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 pre-/post-natal exposure in a 2–generation reproduction study.

3. *Conclusion*. There is a complete toxicity data base for novaluron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA SF was reduced to 1X, based upon the following: As mentioned above, 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 pre-/post-natal exposure in a 2–generation reproduction study. In addition, there is no concern for developmental neurotoxicity resulting from exposure to novaluron, and a developmental neurotoxicity study (DNT) study is not required. Furthermore, the chronic dietary food exposure assessment assumes 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. Finally, there are no proposed or existing uses for novaluron which result in residential exposure.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + 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). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure 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. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An endpoint of concern attributable to a single dose was not identified. Therefore, no acute risk is expected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to novaluron from food will utilize 18% of the cPAD for the U.S. population, 68% of the cPAD for children 1 to 2 years old. There are no residential uses for novaluron that result in chronic residential exposure to novaluron. In addition, there is potential for chronic dietary exposure to novaluron in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO NOVALURON

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.011	18	2.61	0.009	320
Females, (13–49 years old)	0.011	12	2.61	0.009	290
All infants	0.011	31	2.61	0.009	76
Children, (1–2 years old)	0.011	68	2.61	0.009	35
Youth, (13–19 years)	0.011	16	2.61	0.009	280

3. *Short-term risk*. Short-term aggregate exposure takes 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 LOC.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes 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 LOC.

5. *Aggregate cancer risk for U.S. population*. Novaluron has not been shown to be carcinogenic. Therefore, novaluron is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general

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

IV. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits for novaluron.

V. Conclusion

Therefore, the tolerances are established for residues of novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea, in or on fruit, pome (group 11) at 2.0 ppm, apple, wet pomace at 8.0 ppm; cotton, undelinted seed at 0.60 ppm; cotton, gin byproducts at 30 ppm; vegetables, tuberous and corm, subgroup 1C at 0.05 ppm; sheep, horse, cattle, and goat, meat at 0.60 ppm; sheep, horse, cattle, and goat, meat byproducts (except liver and kidney) at 0.60 ppm; sheep, horse, cattle, and goat, fat at 11 ppm; sheep, horse, cattle, and goat, liver at 1.0 ppm; sheep, horse, cattle, and goat, kidney at 1.0 ppm; milk at 1.0 ppm; milk, fat at 20 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; hog, fat at 0.05 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.04 ppm; poultry, fat at 0.40 ppm; and eggs at 0.05 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–2004–0125 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 August 2, 2004.

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 issues(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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *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 Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0125, to: Public Information and Records Integrity Branch, Information Resources and Services 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 Unit I.B.1. 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 issues(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: May 20, 2004.

James Jones,

Director, 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 added to read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide novaluron, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoro-methoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple, wet pomace	8.0
Cattle, fat	11
Cattle, kidney	1.0
Cattle, liver	1.0
Cattle, meat	0.60
Cattle, meat byproducts, except liver and kidney	0.60
Cotton, gin byproducts	30
Cotton, undelinted seed	0.60
Eggs	0.05
Fruit, pome, group 11	2.0
Goat, fat	11
Goat, kidney	1.0
Goat, liver	1.0
Goat, meat	0.60
Goat, meat byproducts except liver and kidney	0.60
Hog, fat	0.05
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	11
Horse, kidney	1.0
Horse, liver	1.0
Horse, meat	0.60
Horse, meat byproducts, except liver and kidney	0.60
Milk	1.0
Milk, fat	20
Poultry, fat	0.40
Poultry, meat	0.03
Poultry, meat byproducts	0.04
Sheep, fat	11
Sheep, kidney	1.0
Sheep, liver	1.0
Sheep, meat	0.60
Sheep, meat byproducts, except liver and kidney	0.60
Vegetables, tuberous and corn, subgroup 1C	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

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

(d) *Indirect or inadvertant residues.* [Reserved]

[FR Doc. 04–12316 Filed 6–1–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7668–4]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion for the Combe Fill North Landfill Superfund site from the National Priorities List.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Region II Office announces the deletion of the Combe Fill North Landfill Superfund site from the National Priorities List (NPL). The Combe Fill North Landfill site is located in Mount Olive Township, Morris County, New Jersey. The NPL constitutes Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300, which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the State of New Jersey, through the Department of Environmental Protection, have determined that all appropriate remedial actions have been completed at the Combe Fill North Site and no further fund-financed remedial action is appropriate under CERCLA. In addition, EPA and the State of New Jersey have determined that the remedial actions taken at the Combe Fill North Site protect public health and the environment without any further monitoring or restriction.

EFFECTIVE DATE: June 2, 2004.

FOR FURTHER INFORMATION CONTACT: Ms. Pamela J. Baxter, Remedial Project Manager, U.S. Environmental Protection Agency, Region II, 290 Broadway, 19th Floor, New York, New York 10007–1866, (212) 637–4416.

SUPPLEMENTARY INFORMATION: To be deleted from the NPL is: the Combe Fill North Landfill Superfund site, Mount Olive Township, Morris County, New Jersey. A Notice of Intent to Delete for the Combe Fill North Landfill site was published in the **Federal Register** on February 24, 2004 (69 FR 8353). The closing date for comments on the Notice of Intent to Delete was March 25, 2004. EPA received no comments regarding this action. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. As described in § 300.425(e)(3) of the NCP, any site or portion thereof deleted from the NPL remains eligible for remedial actions in the unlikely event that conditions at the site warrant such action in the future. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and Recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: May 19, 2004.

Jane M. Kenny,

Regional Administrator—Region II.

■ For the reasons set out in the preamble, part 300, title 40 of Chapter I of the Code of Federal Regulations, is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601–9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR., 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to Part 300 is amended by removing the entry for ''Combe Fill North Landfill, Mount Olive Township, New Jersey.''

[FR Doc. 04–12301 Filed 6–1–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7833]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

DATES: The effective date of each community's suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Mike Grimm, Mitigation Division, 500 C Street, SW., Room 412, Washington, DC 20472, (202) 646–2878.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of