Commodity	Parts per million
Pea, blackeyed, seed	4.0
Pea, southern, seed	4.0
* * * * *	
Turnip, greens	30
* * * * *	
Vegetable, cucurbit, group 9	0.3
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0133; FRL–7306–8]

Clothianidin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on canola, corn, and milk. In addition, tolerances are established for indirect or inadvertent residues of clothianidin in or on nongrass animal feed; cereal grain forage, fodder and straw; grass forage, fodder and hay; and soybean forage and hay. Bayer 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 May 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0133, must be received on or before July 29, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Daniel 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)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0133. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access.* 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 *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of November 14, 2001 (66 FR 57079) (FRL–6809–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6315) by Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120. That notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on canola, seed at 0.01 parts per million (ppm); corn, field, grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, field, forage at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, sweet, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; and milk at 0.01 ppm. Following the review of all the data, tolerances are also required on the following rotational crops, which are used only for livestock feeds. These tolerances do not impact the dietary risk

assessment since these residues are significantly lower than those in feed items from the crops which are treated directly with clothianidin and/or thiamethoxam. Tolerances are established on animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see 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 the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of clothianidin on canola, seed at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, field, forage at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, sweet, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; and milk at 0.01 ppm, animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 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 clothianidin 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
870.3100	90–Day oral toxicity rodents (rats)	NOAEL: 27.9/34.0 milligrams/kilogram/day (mg/kg/day) (male/female) LOAEL: 202.0/254.2 mg/kg/day (male/female: decreased body weight (bwt) and bwt gain)
870.3150	90–Day oral toxicity in nonrodents (dogs)	NOAEL: 19.3/42.1 mg/kg/day (male/female) LOAEL: 40.9/61.8 mg/kg/day (thinness, decreased bwt, bwt gain and anemia (one male); decreased white blood cells, albumin, and total protein (female)
870.3200	21/28–Day dermal toxicity (rats)	NOAEL: 1,000 mg/kg/day (highest dose tested) LOAEL: > 1,000 mg/kg/day
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL: 10 mg/kg/day Maternal LOAEL: 40 mg/kg/day (decreased bwt gain and food consumption) Developmental NOAEL: 125 mg/kg/day Developmental LOAEL: cannot be established
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL: 25 mg/kg/day Maternal LOAEL: 75 mg/kg/day (increased incidences of clinical signs (scant feces and orange urine), mortalities, decreased food consumption, early delivery, abortion, and decreased bwt gain) Developmental NOAEL: 25 mg/kg/day Developmental LOAEL: 75 mg/kg/day (premature deliveries, decreased gravid uterine weights, an increased litter incidence of a missing lobe of the lung and decreased litter average for ossified sternal centra per fetus)

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

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rat)	Parental systemic NOAEL: 31.2/36.8 mg/kg/day (male/female) Parental systemic LOAEL: 163.4/188.8 mg/kg/day (male/female) (decreased bwt, bwt gain and absolute and relative thymus weights) Offspring systemic NOAEL: 9.8/11.5 mg/kg/day (male/female) Offspring systemic LOAEL: 31.2/36.8 mg/kg/day (male/female: decreased bwt gains and delayed sexual maturation (male); decreased absolute thymus weights in F1 pups of both sexes and an increase in stillbirths in both generations) Reproductive NOAEL: 31.2/188.8 mg/kg/day (male/female) Reproductive LOAEL: 163.4/not established mg/kg/day (male/female: decreased sperm motility, and increased number of sperm with detached heads in both generations)
870.4100	Chronic toxicity dogs	NOAEL: 46.4/40.1 mg/kg/day (male/female) LOAEL: Not established/52.9 mg/kg/day (male/female: clinical evidence of anemia in females). Note: dose-related decreases in ALT activity observed in mid- and high-dose males and females
870.4200	Carcinogenicity mice	NOAEL: 171.4/65.1 mg/kg/day (male/female) LOAEL: 254.1/215.9 mg/kg/day (male/female: decreased bwt and bwt gain; decreased food consumption and food efficiency in males at the LOAEL). No evidence of carcinogenicity
870.4300	Chronic feeding/Carcinogenicity rat	NOAEL: 82.0/32.5 mg/kg/day (male/female) LOAEL: 156.5/97.8 mg/kg/day (male/female, decreased bwt and food consumption and altered hepatocellular eosinophilic focus of the liver in both sexes; ovary interstitial gland hyperplasia and increased lymphohistiocytic infiltrate in females; and slightly increased incidences of pelvic mineralization and transitional cell hyperplasia in the kidney, mottled livers of males. No evidence of carcinogenicity
870.5100	Gene Mutation bacterial reverse mutation assay Parent	Small, but significant increase in frequency of histidine revertants in TA1535 strain treated at 1,500 and 5,000 µg/plate +/-S9; still present but weaker in its absence. The positive response was only reproducible at 5,000 µg/plate +/-S9. Clothianidin considered mutagenic under conditions of this test
870.5100	Gene Mutation bacterial reverse mutation assay Parent	No mutagenic activity in bacteria (*Salmonella typhimurium* and *Escherichia coli*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay Parent	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay Parent	Only TA 1535 tested. No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay BN0335E2 metabolite	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay TZMU metabolite	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay methyl guanidine intermediate	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay TZNG metabolite	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay TMG metabolite	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay

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

Guideline No.	Study Type	Results
870.5100	Gene Mutation bacterial reverse mutation assay BN0230M metabolite	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay MAI metabolite	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation bacterial reverse mutation assay N-Methylnitroguanid in intermediate	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation - bacterial reverse mutation assay TI 435-Triazan intermediate	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5100	Gene Mutation - bacterial reverse mutation assay TI 435-CCMT- Adduct	No mutagenic activity in bacteria (*Salmonella typhimurium*) under conditions of this assay
870.5300	Gene Mutation - *in vitro* mammalian cell gene mutation test (L5178Y TK +/- mouse lymphoma cells) Parent	Increases in mutant frequency with and without S9 at dose levels that were cytotoxic. The observed response was primarily due to small colony formation, indicating clastogenic activity
870.5300	Gene Mutation - *in vitro* mammalian cell gene mutation test (V79-HPRT Assay) Parent	No increase in mutant frequency under the conditions of the study
870.5395	Cytogenetics - mammalian erythrocyte micronucleus test Parent	Clothianidin is considered to be neither clastogenic nor aneugenic under these test conditions
870.5375	Cytogenetics - *in vitro* mammalian chromosome aberration test (CHL Cells) Parent	Significant increases in frequency of cells with structural aberrations. Predominant types were chromatid breaks and exchanges. There was, however, no clear indication of a dose-related response in either the presence or absence of S9 activation
870.5500	Other Effects - DNA Repair Test in *Bacillus subtillis* Parent	No potential for DNA damage under these conditions
870.5550	Other Effects - (UDS) in Mammalian Cells in Culture Parent	No evidence (or a dose related positive response) that UDS was induced
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL: Not established LOAEL: 100 mg/kg (FOB: decreased arousal and decreased motor and locomotor activity)
870.6200	Subchronic neurotoxicity screening battery (rat)	NOAEL: 60.0/71.0 mg/kg/day (male/female) LOAEL: 177.0/200.1 mg/kg/day (male/female: Slightly decreased food consumption, bwt and bwt gains)
870.6300	Developmental neurotoxicity (rat)	Maternal NOAEL: 42.9 mg/kg/day Maternal LOAEL: 142 mg/kg/day (decreased bwt, bwt gains, and food consumption) Offspring NOAEL: 12.9 mg/kg/day Offspring LOAEL: 42.9 mg/kg/day (decreased bwt and bwt gains)
870.7485	Metabolism and pharmacokinetics (rat)	Overall recovery: 95–100%. Readily absorbed and excreted within 96 hours following a single 2.5 mg/kg bwt or repeated oral dose of 25 mg/kg bwt, but at a dose of 250 mg/kg, absorption became biphasic and was saturated

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics (mouse)	Of the administered radioactivity, 98.7–99.2% was recovered. Readily absorbed and excreted within 168 hours following a single oral dose of 5 mg/kg bwt
870.7600	Dermal Penetration - monkey	Dermal absorption as the sum of urinary and fecal excretion and Cage/Pan/Chair Wash, Debris was 0.24 (+ 0.11) as percent of dose. Adjustment of the direct absorption determination was not necessary because recovery from the dermal dose was ≤90%. A value of 1% dermal absorption was considered appropriate for use in risk assessment. This estimation takes into account any variability that would have likely occurred with testing several dose levels
	Special study: Neurotoxicity and pharmacology mouse	NOAEL: 25 mg/kg/day (male/female) LOAEL: 50 mg/kg bw mg/kg/day (transient signs of decreased spontaneous motor activity, tremors, and deep respirations)

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. EPA has concluded that the toxicology database for clothianidin is not complete. Due to evidence of effects on the immune system and that juvenile rats appear to be more susceptible to these effects, EPA has determined that testing should be conducted to assess immune system function in adults and in young animals following developmental exposures. Therefore, a 10X database UF is to be applied to all dietary exposure endpoints for the lack of a developmental immunotoxicity study.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, 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 FQPA SF.

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 is expressed as 1×10^{-6} or one in a million). 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 clothianidin used for human risk assessment is shown in Table 2 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF[1]	Special FQPA SF[2] and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	Developmental NOAEL = 25 UF = 1000[1] Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷FQPA SF= 0.025 mg/kg	Developmental rabbit study Developmental LOAEL = 75 mg/kg/day based on an increased litter incidence of a missing lobe of the lung
Acute Dietary (General population)	NOAEL = 25 UF = 1000[1] Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Special Neurotoxicity/Pharmacology Study in Mice and Rats LOAEL = 50 mg/kg based on transient signs of decreased spontaneous motor activity, tremors and deep respirations

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

Exposure Scenario	Dose Used in Risk Assessment, UF[1]	Special FQPA SF[2] and LOC for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	Offspring NOAEL= 9.8 UF = 1000[1] Chronic RfD = 0.0098 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.0098 mg/kg/day	2–Generation Reproduction Study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean bwt gain and delayed sexual maturation, decreased absolute thymus weights in F1 pups and an increase in stillbirths in both generations
Cancer (oral, dermal, inhalation)	Classification: Not likely		

1 An additional 10X database uncertainty factor for lack of a developmental immunotoxicity study.
2 The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Currently there are no tolerances established for clothianidin alone on any commodity. However, clothianidin is a major metabolite of thiamethoxam, and tolerances for the combined residues of thiamethoxam and its metabolite clothianidin have been established under 40 CFR part 180.565 for both plant and livestock commodities. Tolerances for thiamethoxam range from 0.02 ppm to 1.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from clothianidin 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. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption 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 acute exposure assessments: The acute analysis was a conservative, Tier I assessment which was based on tolerance level residues and the assumption of 100% crop treated. Although the only proposed uses for clothianidin are on canola and corn, clothianidin is a major metabolite of thiamethoxam which has many registered uses and several pending uses. As a result, residues of clothianidin which would theoretically result from the metabolism of thiamethoxam were included in the analysis. In crop field trials and in animal feeding studies, the quantities of both clothianidin and thiamethoxam were measured. The ratio of clothianidin to thiamethoxam in each commodity was multiplied by the respective thiamethoxam tolerance level to arrive at the theoretical maximum clothianidin residue level which would be present. These maximum clothianidin residues were used in the acute analysis. For the commodities which have both thiamethoxam tolerances and proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, and milk), the proposed clothianidin tolerances were added to the residues which result from use of thiamethoxam.

As this is a Tier I assessment, dietary exposure and risk at the 95th percentile of exposure are reported. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the aPADs are all below 100%). The most highly exposed population subgroup is children 1 to 2 years of age, which utilizes 16% of the aPAD.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis was a conservative, Tier I assessment which was based on tolerance level residues and the assumption of 100% crop treated. As stated previously, although the only proposed uses for clothianidin are on canola and corn, clothianidin is a major metabolite of thiamethoxam which has many registered uses and several pending uses. As a result, residues of clothianidin which would theoretically result from the metabolism of thiamethoxam were included in the analysis. In crop field trials and in animal feeding studies, the quantities of both clothianidin and thiamethoxam were measured. The ratio of clothianidin to thiamethoxam in each commodity was multiplied by the respective thiamethoxam tolerance level to arrive at the theoretical maximum clothianidin residue level which would be present. These maximum clothianidin residues were used in the chronic analysis. For the commodities which have both thiamethoxam tolerances and proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, and milk), the proposed clothianidin tolerances were added to the residues which result from use of thiamethoxam.

The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the chronic population adjusted doses (cPADs) are all below 100%). The most highly exposed population subgroup is children 1 to 2 years of age, which utilizes 18% of the cPAD.

iii. *Cancer*. EPA has determined that clothianidin is not likely to be a human carcinogen and EPA, therefore, does not expect it to pose a cancer risk. As a result, a quantitive cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clothianidin 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 clothianidin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir.

The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models 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 clothianidin, they are further discussed in the aggregate risk sections.

Based on the FIRST and SCI-GROW models, the EECs of clothianidin for acute exposures are estimated to be 3.97 parts per billion (ppb) for surface water and 1.46 ppb for ground water. The EECs for chronic exposures are estimated to be 2.14 ppb for surface water and 1.46 ppb for ground 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). Clothianidin is not registered for use on any sites that would result in residential exposure. Clothianidin is a major metabolite of the insecticide thiamethoxam in plants and animals. Since there are also no residential uses of thiamethoxam, possible residential exposure to clothianidin due to thiamethoxam uses is not expected.

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

EPA does not have, at this time, available data to determine whether clothianidin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, clothianidin 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 clothianidin 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. No quantitative or qualitative susceptibility was observed in either of the developmental rat or rabbit studies. Quantitative susceptibility was observed in both the reproduction and developmental neurotoxicity studies; however, the degree of concern for these studies is low because the observed effects are well characterized and there are clear NOAELs/LOAELs in each case. In addition, the endpoint of concern is the one that is being used for short-, intermediate- and long-term dietary and non-dietary exposure risk assessments. There are no residual uncertainties. Therefore, there are no to low concerns with regard to prenatal and/or postnatal toxicity.

3. *Conclusion*. The toxicology database for clothianidin is not complete for FQPA purposes. A complete complement of acceptable developmental, reproduction, developmental neurotoxicity, mammalian neurotoxicity and special neurotoxicity studies are available; however, due to evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin data base, and since juvenile rats in the 2–generation reproduction study appear to be more susceptible to these effects, EPA has determined that testing should be conducted to assess immune system function in adults and in young animals following developmental exposures. As noted previously, a 10X database UF was applied because of the lack of this study.

The FQPA factor is removed because there are no to low concerns and no residual uncertainties with regard to prenatal and/or postnatal toxicity. As stated above, no quantitative or qualitative susceptibility was observed in either of the development rat or rabbit studies, and the observed effects are well characterized and there are clear NOAELs/LOAELs in the reproduction and developmental neurotoxicity studies. In addition, the acute and chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assessments, acute and chronic exposures/risks will not be underestimated. Furthermore, the dietary drinking water assessment (Tier I estimates) uses values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. Finally, there are no residential uses for either clothianidin or thiamethoxam.

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 the model estimates of a pesticide's concentration

in water (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 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to clothianidin will occupy 7.3% of the aPAD for the U.S. population, 5.4% of the aPAD for females 13 years and older, 11% of the aPAD for all infants (less than 1 year old) and 16% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOTHIANIDIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	0.025	7.3	3.97	1.46	810
All infants (< 1 year old)	0.025	11	3.97	1.46	220
Children (1–2 years old)	0.025	16	3.97	1.46	210
Females (13–49 years old)	0.025	5.4	3.97	1.46	710
Adults (50+ years old)	0.025	6.0	3.97	1.46	820

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clothianidin from food will utilize 5.9% of the cPAD for the U.S. population, 9.8% of the cPAD for all infants (less than 1 year old) and 18% of the cPAD for children 1 to 2 years old. There are no residential uses for clothianidin that result in chronic residential exposure to clothianidin. In addition, there is potential for chronic dietary exposure to clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOTHIANIDIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
General U.S. Population	0.0098	5.9	2.14	1.46	320
All Infants (< 1 year old)	0.0098	9.8	2.14	1.46	88
Children (1–2 years old)	0.0098	18	2.14	1.46	80
Females (13–49 years old)	0.0098	4.6	2.14	1.46	280
Adults (50+ years old)	0.0098	4.9	2.14	1.46	320

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). Clothianidin and thiamethoxam are 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). Clothianidin and thiamethoxam are 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*. Clothianidin has been classified as a ''not likely human carcinogen.'' Therefore, it 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 clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example - liquid chromotography) 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

No Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established for residues of clothianidin.

C. Conditions

A developmental immunotoxicity study with comparative measures between the pups and the parents is required.

V. Conclusion

Therefore, tolerances are established for residues of clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on canola, seed at 0.01 ppm ; corn, field, grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, field, forage at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, sweet, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; and milk at 0.01 ppm, animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the 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–2003–0133 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 29, 2003.

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–2003–0133, 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 the 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 the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 19, 2003.

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), 346(a) and 371.

■ 2. Section 180.586 is added to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities:

Commodity	Parts per million
Canola, seed	0.01
Corn, field, forage	0.10
Corn, field, grain	0.01
Corn, field, stover	0.10
Corn, pop, grain	0.01
Corn, pop, stover	0.10
Corn, sweet, forage	0.10
Corn, sweet, kernel plus cob with husk removed	0.01
Corn, sweet, stover	0.10
Milk	0.01

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

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

(d) *Indirect and inadvertant residues.* Tolerances are established for the indirect or inadvertent residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities when present therein as a result of the application of clothianidin to crops listed in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass	0.02
Grain, cereal, forage, fodder and straw	0.02
Grass, forage, fodder and hay	0.02
Soybean, forage	0.02
Soybean, hay	0.02

[FR Doc. 03–13564 Filed 5–29–03; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, and 485

[CMS–1204–CN]

RIN 0938–AL21

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the final rule with comment period published in the **Federal Register** on December 31, 2002, entitled, ''Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations''.

EFFECTIVE DATE: This rule is effective March 1, 2003.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786–3355.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 02–32503 of December 31, 2002 (67 FR 79966), there were a number of technical errors that are identified and corrected in the Correction of Errors section below. Additionally there are various revisions to Addenda B, C, D and E. The provisions in this correction notice are effective as if they had been included in the document published December 31, 2002.

Discussion of Addenda B, C, D and E

1. In Addendum B, we assigned incorrect status indicators for the following CPT codes: Page 80111 for CPT code 67221; page 80143 for CPT codes 90723, 90740, 90743, 90744, 90746, 90747 and 90748; page 80158 for CPT codes 99026 and 99027; and page 80166 for HCPCS code J3370. We assigned incorrect status indicators and RVUS for the following CPT and HCPCS codes: Page 80147 for CPT code 92597; page 80149 for CPT codes 93315, 99315–TC, 99317 and 93317–TC; page 80156 for 95951 and 95951–TC, page 80158 for CPT code 99026 and 99027 and page 80163 for G0125 and G0125–TC. We also erroneously assigned RVUs to the following HCPCS codes that are not used for Medicare payment: Page 80164 for G0219 and G0219–26; page 80165 for G0255 and G0255–26. These corrections are reflected in correction number 12 to follow.

2. We indicated the incorrect global period in Addenda B and C for the following CPT codes: Page 80100 for CPT code 58550; pages 80074 and 80167 for CPT codes 33224; and page 80134 for CPT codes 77789, 77789–26 and 77789–TC. The corrected global period is in correction number 13 to follow.

3. In Addenda B and C, on pages 80044, 80165 and 80170, we erroneously assigned RVUs to a CPT code 0020T which is an emerging technology code and also created two new HCPCS codes (G0279 and G0280) with payments based on our valuation of this CPT code. However, assignment of RVUs for this CPT code is contrary to national policy established in the November 1, 2001 (66 FR 55269), final rule which stated that we would provide payment for emerging technology codes as determined by the carrier. In addition, based on the creation of these two G codes, we are not recognizing CPT code 0019T for Medicare purposes. Corrections for these services are in correction number 14.

4. In Addenda B on page 80097, incorrect work and practice expense RVUS were assigned to CPT code 53853. In addition, on page 80110 the RVUs listed under non-facility total and facility total were incorrect for the following codes: 66710, 66720, 66761 66762 and 66770. These corrections are reflected in correction number 15.

5. In Addenda B and C, incorrect practice expense RVUs were assigned for the following CPT codes: Page 80044 for CPT codes 10021 and 10022; page 80060 for CPT 26587; page 80084 for CPT code 42820; page 80092 for CPT codes 50080, 50081, 50236, 50240; page 80093 for CPT codes 50553, 50555, 50557, 50561, 50684 and 50690; page 80094 for CPT codes 50953, 50955, 50957, 50961, 51010, 51605, 51610, 51710, 51726 and 51726–TC; page 80095 and 80168 for CPT codes 51772, 51772–TC, 51784, 51784–TC, 51785, 51785–TC, 51792, 51792–TC, 51795, 51795–TC, 51798, 52000, 52005, 52010, 52204, 52214, 52224, 52265, 52270, 52275, 52276, 52281, 52282, 52283, 52285, 52310, 52315, 52317, 52330 and 52332; page 80096 for CPT codes 52647, 53025, 53040, 53080, 53085, 53200, 53265 and 53270; page 80093 for CPT codes 53850, 53852, 54000, 54001, 54015, 54055, 54060, 54105, 54111, 54115, 54120, 54125, 54130, 54135, 54160, 54205, 54300, 54304, 54308, 54312, 54324, 54328, 54332, 54360 and 54430; page 80098 for CPT codes 54500, 54700, 55100, 55250, 55450, and 55700; page 80099 for CPT code 55873; page 80100 for CPT code 58340; page 80109 for CPT code 65220; page 80110 for CPT code 66740; page 80110 for CPT codes 66821 and 66984; page 80111 for CPT codes 67820 and 67825; page 80117 for CPT codes 71275 and 71275–TC; page 80119 for CPT codes 72191 and 72191–TC; page 80120 for CPT codes 73206 and 73206–TC; page 80121 for CPT codes 73706 and 73706–TC; page 80122 for CPT codes 74175 and 74175–TC; page 80130 for CPT codes 76519 and 76519–TC; page 80141 for CPT code 88141; page 80145 for CPT codes 91122, 91122–TC, 92014, 92081, 92081–TC, 92083, 92083–TC, 92135 , 92135–TC, 92235; page 80146 for CPT codes 92235–TC, 92250 and 92250–TC; page 80148 for CPT code 93012; page 80153 for CPT codes 94014 and 94015; page 80163 for HCPCS codes G0124 and G0141; page 80165 and 80170 for HCPCS codes G0275, G0278 and G0281; page 80166 and 80170 for HCPCS codes G0283, G0289 and P3001. The corrected RVUs are in item number 16.

6. In Addendum D, on page 80171, the carrier numbers listed for Ohio and West Virginia are incorrect. The corrected numbers are reflected in number 17 to follow.