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: September 15, 2005.

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 180.614 is added to read as follows:

§ 180.614 Kasugamycin; tolerances for residues.

(a) *General.* Tolerances are established for residues of kasugamycin, 3-O-[2-amino-4-[(carboxyiminomethyl)amino]-2,3,4,6-tetradeoxy-α-D-arabino-hexopyranosyl]-D-chiro-inositol in or on the following raw agricultural commodity:

Commodity	Parts per million
Vegetable, fruiting group 8[1]	0.04

[1]There is no U.S. registration as of September 1, 2005.

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

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

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

[FR Doc. 05–19061 Filed 9–22–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0185; FRL–7736–3]

Amicarbazone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of amicarbazone and its metabolites in or on field corn and livestock commodities and indirect or inadvertent residues of amicarbazone and its metabolites in alfalfa, cotton, soybean and wheat. Arysta Lifescience North American Corporation (perviously known as Arvesta Corporation) 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 September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0185. 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, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:

Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@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/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of January 22, 2004 (69 FR 3138) (FRL–7339–3), 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 0F6131) by Arysta Lifescience North American Corporation, 100 First Street, Suite 1700; San Francisco, CA 94105. The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the herbicide amicarbazone, 4-amino-4,5-dihydro-N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolities DA amicarbazone (N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H,2,4-triazole-1-carboxamide) and iPr-2-OH DA amicarbazone (N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide), in or on the raw agricultural commodities alfalfa forage at 0.04 parts per million (ppm); alfalfa hay at 0.06 ppm; corn forage at 0.8ppm; corn grain, at 0.05 ppm; corn stover at 0.5 ppm; cotton gin by-product at 0.2 ppm; cottonseed hulls at 0.01 ppm; cottonseed meal at 0.01 ppm; cottonseed refined oil at 0.01 ppm; cotton undelinted seed at 0.04 ppm; soybean forage at 2.5 ppm; soybean hay at 7.0 ppm; soybean hulls at 0.2 ppm; soybean meal at 0.25 ppm; soybean oil at 0.01 ppm; soybean seed at 0.6 ppm; wheat bran at 0.08 ppm; wheat flour at 0.05 ppm; wheat forage at 0.6 ppm; wheat germs at 0.05 ppm; wheat grain at 0.09 ppm; wheat hay at 0.9 ppm; wheat middlings at 0.05 ppm; wheat shorts at 0.06 ppm; wheat straw at 0.4 ppm; sugarcane at 0.15 ppm; sugarcane molasses at 0.8 ppm; meat (cattle, goats, hogs, horses, and sheep) at 0.01 ppm; meat byproducts (cattle, goats, hogs, horses,and sheep) at 0.2 ppm; and milk at 0.01 ppm respectively.

Due to a lack of field trial data on sugarcane, tolerances on sugarcane and sugarcane molasses are not being established at this time.

One comment was received in response to the notice filing. B. Sachau objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing conducted on animals have absolutely no validity and are cruel to the test animals. EPA's response to these comments is contained in Unit IV.C.

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 a tolerance for combined residues of amicarbazone [4-amino-4, 5-dihydro- N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on corn, field, forage at 0.80 ppm; corn, field, grain at 0.05 ppm; corn, field, stover at 1.0 ppm; cattle, fat at 0.01 ppm; cattle, liver at 1.0 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.10 ppm; goat, fat at 0.01 ppm; goat, liver at 1.0 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.1

ppm; hog, fat at 0.01 ppm; hog, liver at 0.1 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.01 ppm; horse, fat at 0.01 ppm; horse, liver at 1.0 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.10 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, liver at 1.0 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts, except liver at 0.10 ppm; poultry, liver at 0.01 ppm. EPA can also make a determination on aggregate exposure for the establishment of tolerances for the indirect or inadvertent residues of amicarbazone and its metabolites DA amicarbazone and iPr-2-OH DA amicarbazone, calculated as amicarbazone, in or on the following raw agricultural commodities when present therein as a result of the application of amicarbazone to field corn: Alfalfa, forage at 0.05 ppm; alfalfa, hay at 0.10 ppm; cotton, undelinted seed at 0.07 ppm; cotton, gin byproducts at 0.30 ppm; soybean, forage at 1.50 ppm; soybean, hay at 5.0 ppm; soybean, seed at 0.80 ppm; wheat, forage at 0.50 ppm; wheat, hay at 1.0 ppm; wheat, grain at 0.10 ppm; wheat, straw at 0.50 ppm; wheat, grain, milled byproducts at 0.15 ppm.

EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by amicarbazone 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 = 33/38 milligram/kilogram/day (mg/kg/day) LOAEL = 67/78 mg/kg/day based on decreased bodyweight (BW) female and overall (weeks 1–13) bodyweight gain (BWG), decreased red cell indices, clinical chemistry (increased cholesterol, T4 and T3 males, O-demethylase females, N-demethylase males), increased relative liver weights females, and histopathology effects in males (minimal hepatocytomegaly and minimal pigmentation in the spleen)
870.3150	90–Day oral toxicity - nonrodents (dogs)	NOAEL = 6.28 mg/kg/day LOAEL = 24.99 mg/kg/day based on increased thyroid vacuolization and decreased food consumption and glucose in females; increased platelets, phosphate, bile acids, absolute and relative liver weights, and lymphoid hyperplasia of the gall bladder in males; and decreased albumin and increased triglycerides, N-demethylase, and O-demthylase in both sexes.
870.3200	21/28–Day dermal toxicity	NOAEL = 1,000 mg/kg/day LOAEL = Not Observed
870.3700	Prenatal developmental in rats	Maternal NOAEL = 15 mg/kg/day LOAEL = 100 mg/kg/day based on decreased BW/BWG and food consumption, and increased incidences of hard stools. Developmental NOAEL = 15 mg/kg/day LOAEL = 100 mg/kg/day based on multiple skeletal development retardations (incomplete ossification/unossification was observed in parietal bones, interparietal bones, supraoccipital bones, squamosal bones, zygoma, pubis, xiphoid, and fontanelle
870.3700	Prenatal developmental in rabbits	Maternal NOAEL = 5 mg/kg/day LOAEL = 20 mg/kg/day based on decreased BWG during treatment. Developmental NOAEL = 20 mg/kg/day LOAEL = 70 mg/kg/day based on decreased fetal BW, and increased incidences of incomplete ossification of the 5th medial phalanx (bilateral) and the 13th caudal vertebra, and slightly thick ribs.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 6.4/7.3 mg/kg/day LOAEL = 33.9/38.7 mg/kg/day based on decreased BW/BWG in both sexes. Reproductive NOAEL = 73.2/84.0 mg/kg/day LOAEL = Not Observed Offspring NOAEL = 6.4/7.3 mg/kg/day LOAEL = 33.9/38.7 mg/kg/day based on decreased pup BW and overall decreased BWG.

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

Guideline No.	Study Type	Results
870.4100	Chronic toxicity in rodents (rats)	NOAEL = 2.3/2.7 mg/kg/day LOAEL = 25.3/29.5 mg/kg/day based on decreased BW in females and BWG in both sexes. At the doses tested there was not a treatment related increase in tumor incidence when compared to control. Dosing was considered adequate based on decreased BW in females and BWG in both sexes.
870.4100	Chronic toxicity dogs (beagle)	NOAEL =2.5/2.3 mg/kg/day LOAEL = 8.9/8.7 mg/kg/day based on effects on the liver, including increased absolute and relative liver weights, and O-demethylase in males; increased globulin and cytochrome P-450 in females; and increased triglycerides and cholesterol in both sexes.
870.4300	Carcinogenicity-mice	NOAEL = 244.7/275.0 mg/kg/day LOAEL = 709.0/806.3 mg/kg/day based on decreased BW and BWG in both sexes, and subclinical anemia, and hemosiderin pigmentation of the spleen in males. no evidence of carcinogenicity At the doses tested there was not a treatment related increase in tumor incidence when compared to control. Dosing was considered adequate based on decreased BW and BWG in both sexes, and subclinical anemia, and hemosiderin pigmentation of the spleen in males.
870.5100	Bacterial reverse mutation test	There was no evidence of induced mutant colonies over background.
870.5100	Bacterial reverse mutation test	There was no evidence of induced mutant colonies over background.
870.5100	Bacterial reverse mutation test	There was no evidence of induced mutant colonies over background.
870.5300	*In vitro* mammalian cell gene mutation test	There was no evidence that MKH3586 induced mutant colonies over background in the presence or absence of S9-activation.
870.5375	*In vitro* mammalian chromosome aberration test	There was no evidence of chromosome aberration induced over background in the presence or absence of S9-activation.
870.5395	Mammalian erythrocyte micronucleus test	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow at any treatment time.
870.6200	Acute neurotoxicity screening battery in rats (Fischer-344)	NOAEL = 10 mg/kg/day LOAEL = 20 mg/kg/day based on eyelid ptosis, decreased approach response (both sexes), and red nasal staining in males. A series of acute neurotoxicity studies were performed, the NOAEL for this study comes from 45121527.
870.6200	Subchronic neurotoxicity screening battery in rats (Fischer-344)	**Female:** NOAEL = 7.8 mg/kg/day LOAEL = 38.2 mg/kg/day based on decreased BW and overall BWG in females. **Male:** NOAEL = 66.5 mg/kd/day LOAEL = was not observed for males.
870.6300	Developmental neurotoxicity in rats	Maternal NOAEL = 8 mg/kg/day LOAEL = 39 mg/kg/day based primarily on decreased feed efficiency (combination of decreased BWG and increased food consumption) during lactation. Offspring NOAEL = 39 mg/kg/day LOAEL = 91 mg/kg/day based on decreased BWG.
870.7485	Metabolism and pharmacokinetics	95% of the radioactive dose was recovered within 72 hours following dosing. The majority of the dose was recovered from the urine within 24 hours (64%), indicating substantial absorption. Fecal excretion accounted for 27% of the dose within 24 hours. Major metabolites were DA MKH, N-methyl DA MKH, and decarboxamide.

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	91% of the radioactive dose was recovered within 96 hours. Urinary excretion accounted for 70% of the radioactive dose within 12 hours, showing substantial absorption. Only 8% of the radioactive dose was excreted via the feces within 24 hours.
Non-guideline	Subchronic mechanistic feeding in rats	Thyroid hormones were increased in the >19.4 mg/kg/day females and 40.0 mg/kg/day males. However, thyroid to blood ratios of ^{125}I in treated groups were comparable to negative controls, indicating there was no impairment of thyroid hormone synthesis. Thus, the differences in thyroid hormones is probably due to metabolism at an extra-thyroidal site. The liver was implicated as this site because liver weights and UDP-glucuronosyltransferase activity were increased.
Non-guideline	*In vitro* studies on enzymes of thyroid hormone regulation	MKH 3586 does not affect the iodide organification step of thyroid hormone synthesis or the peripheral metabolism of thyroid hormones via Type I or Type II deiodinases *in vivo*. These findings support the subchronic mechanistic studies in rats which indicate that upregulation of UDP-glucuronosyl transferase in the liver may account for alterations in thyroid hormone profile.
Non-guideline	Behavioral study in rats	The following clinical signs were observed: Sedation, ptosis, salivation. Additionally at the HDT, piloerection, Straub phenomenon, and prone position were observed. The effects were observed at 30 minutes post dose, and no effect was observed at 150 minutes post dose, with the higher dose groups showing greater persistence of effects. A dose- and time-dependent effect was demonstrated on motor activity - decreased travel distance, increased resting time, and decreased rearing.
Non-guideline	Study of central nervous system safety pharmacology in mice	The data indicate that a single dose of MKH 3586 at 100 mg/kg causes minimal CNS functional impairment, characterized by increased reaction times to nociceptive stimuli, reduced traction force, impaired motor coordination, sedation, partial ptosis, and a mild anticonvulsive effect.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

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 = NOAE/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 non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. 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}), one in a 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 amicarbazone used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AMICARBAZONE FOR USE IN HUMAN RISK ASSESSMENTS

Exposure Scenario	Dose Used in Risk Assessment UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–49 years of age)	NOAEL = 10 mg/kg/day UF = 100X Acute RfD = 0.10 mg/kg/day	Special FQPA SF = 1X aPAD = 0.10 mg/kg/day	Acute neurotoxicity screening battery LOAEL = 20 mg/kg/day, based on eyelid ptosis, decreased approach response, red nasal staining in male rats.
Acute dietary (general population)	NOAEL = 10 mg/kg/day UF = 100X Acute RfD = 0.10 mg/kg/day	Special FQPA SF = 1X aPAD = 0.10 mg/kg/day	Acute neurotoxicity screening battery LOAEL = 20 mg/kg/day, based on eyelid ptosis, decreased approach response, red nasal staining in male rats.
Chronic dietary (all populations)	NOAEL = 2.3 mg/kg/day UF = 100X Chronic RfD = .023 mg/kg/day	Special FQPA SF = 1X cPAD = 0.023 mg/kg/day	Chronic rat and chronic dog LOAEL = 25.3 and 8.7, respectively, based on rat - decreased BW and BWG dog - liver effects, including increased absolute and relative liver weights, and O-demethylase in male dogs; increased globulin and cytochrome p450 in female dogs; and increased triglycerides and cholesterol in both sexes
Dermal (all durations)	Not required: No systemic toxicity by dermal route was seen at the limit dose. Evidence of low dermal absorption.		
Inhalation short-term (1 - 30 days)	NOAEL = 6.28 mg/kg/day	LOC for MOE = 100	90–Day oral toxicity in dogs LOAEL = 24.99 mg/kg/day, based on increased thyroid vacuolization and decreased food consumption and glucose in females; increased platelets, phosphate, bile acids, absolute and relative liver weights, and lymphoid hyperplasia of the gall bladder in males; and decreased albumin and increased triglycerides, N-demethylase, and O-demethylase in both sexes
Inhalation intermediate-term (1-6 months)	NOAEL = 6.28 mg/kg/day	LOC for MOE = 100	90–Day oral toxicity in dogs LOAEL = 24.99 mg/kg/day, based on increased thyroid vacuolization and decreased food consumption and glucose in females; increased platelets, phosphate, bile acids, absolute and relative liver weights, and lymphoid hyperplasia of the gall bladder in males; and decreased albumin and increased triglycerides, N-demethylase, and O-demethylase in both sexes
Cancer (oral, dermal, inhalation)	Classification: There was no treatment related increase in tumor incidence when compared to control. Dosing was considered adequate. This chemical is not likely to be a carcinogen.		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have been established in 40 CFR part 180 previously for the combined residues of amicarbazone, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from amicarbazone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption 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 acute exposure assessments: For the acute analyses, tolerance-level residues were assumed for all food commodities with proposed amicarbazone tolerances, and it was assumed that 100% of all of the crops included in the analysis were treated. The DEEM™ analyses included drinking water in addition to the food sources of residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM 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 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the chronic analyses tolerance-level residues were assumed for all food commodities with proposed amicarbazone tolerances, and it was assumed that 100% of all of the crops included in the analysis were treated. As with the acute analyses, drinking water was included in the assessment.

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

Based on the FIRST and SCI-GROW models, the estimated environmental concentrations (EECs) of amicarbazone for acute exposures are estimated to be 21.4 parts per billion (ppb) for surface water and 102.9 ppb for ground water. The EECs for chronic exposures are estimated to be 13.4 ppb for surface water and 102.9 ppb for ground water. The ground water EEC was used in both the acute and chronic DEEM analyses described earlier in this section.

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).

Amicarbazone is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 amicarbazone and any other substances and amicarbazone 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 amicarbazone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with amicarbazone. There is no evidence of increased susceptibility of rats in the reproduction study with amicarbazone. EPA concluded that there are no residual uncertainties for prenatal and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for amicarbazone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency concluded that there was reliable data to remove the 10X children's safety factor based upon the following: The toxicity database showed no increase in susceptibility in fetuses and pups with *in utero* and post-natal exposure; the dietary exposure assessment is based on HED-recommended tolerance-level residues, assumes 100% crop treated for all commodities, and utilizes high-end estimates of concentrations in water; and there are no residential uses proposed for this chemical at this time.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and drinking water to amicarbazone will occupy 7% of the aPAD for the U.S. population, 6% of the aPAD for females 13 years and older, 23% of the aPAD for the all infant subpopulation, which is the subpopulation with the greatest exposure, and 12% of the aPAD for children 1–2 years old. Therefore, EPA does not expect the acute aggregate risk exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to amicarbazone from food and drinking water will utilize 14% of the cPAD for the U.S. population, 39% of the cPAD for for the all infant subpopulation, which is the subpopulation with the greatest exposure, and 26% of the cPAD for children 1–2 years old. There are no residential uses for amicarbazone that result in chronic residential exposure to amicarbazone. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

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). Amicarbazone is not registered for use on any sites that would result in residential exposure. Therefore, the chronic 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). Amicarbazone 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 does not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population*. A cancer dietary exposure analysis was not performed because the

Agency determined that amicarbazone was not likely to cause cancer.

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 amicarbazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry) is available to enforce the tolerance expression. The methods for both plant and livestock commodities 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 residue limits for amicarbazone.

C. Response to Comments

Ms. Sachau's comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to amicarbazone, including all anticipated dietary exposures and all other exposures for which there is reliable information. This comment as well as her comments regarding animal testing have been responded to by EPA on several occasions. 70 FR 1349 (January 7, 2005)(FRL–7691–4); 69 FR 63083, (October 29, 2004)(FRL–7681–9).

V. Conclusion

Therefore, tolerances are established for combined residues of amicarbazone [4-amino-N-(1,1-dimethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on corn, field, grain at 0.05 ppm; corn, field, forage at 0.80 ppm; corn, field, stover at 1.0 ppm; cattle, fat at 0.01 ppm; cattle, liver at 1.0 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.10 ppm; goat, fat at 0.01 ppm; goat, liver at 1.0 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.1 ppm; hog, fat at 0.01 ppm; hog, liver at 0.1 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.01 ppm; horse, fat at 0.01 ppm; horse, liver at 1.0 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.10 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, liver at 1.0 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts, except liver at 0.10 ppm; poultry, liver at 0.01 ppm.

Tolerances are also established for the indirect or inadvertent residues of amicarbazone and its metabolites DA amicarbazone and iPr-2-OH DA amicarbazone, calculated as amicarbazone, in or on the following raw agricultural commodities when present therein as a result of the application of amicarbazone to field corn: Alfalfa, forage at 0.05 ppm; Alfalfa, hay at 0.10 ppm; Cotton, undelinted seed at 0.07 ppm; Cotton, gin byproducts at 0.30 ppm; Soybean, forage at 1.50 ppm; Soybean, hay at 5.0 ppm; Soybean, seed at 0.80 ppm; Wheat, forage at 0.50 ppm; Wheat, hay at 1.0 ppm; Wheat, grain at 0.10 ppm; Wheat, straw at 0.50 ppm; Wheat, grain, milled byproducts at 0.15 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0185 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 November 22, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIA, you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0185, 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 **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 12, 2005.

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 180.615 is added to subpart C to read as follows:

§ 180.615 Amicarbazone; tolerances for residues

(a) *General.* Tolerances are established for combined residues of the herbicide, amicarbazone [4-amino-4, 5-dihydro- N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.01
Cattle, liver	1.0
Cattle, meat	0.01
Cattle, meat byproducts, except liver	0.10
Corn, field, forage	0.80
Corn, field, grain	0.05
Corn, field, stover	1.0
Goat, fat	0.01

Commodity	Parts per million
Goat, liver	1.0
Goat, meat	0.01
Goat, meat byproducts, except liver	0.10
Hog, fat	0.01
Hog, liver	0.10
Hog, meat	0.01
Hog, meat byproducts, except liver	0.01
Horse, fat	0.01
Horse, liver	1.0
Horse, meat	0.01
Horse, meat byproducts, except liver	0.10
Milk	0.01
Sheep, fat	0.01
Sheep, liver	1.0
Sheep, meat	0.01
Sheep, meat byproducts, except liver	0.10
Poultry, liver	0.10

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of amicarbazone [4-amino-4, 5-dihydro-N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on the following commodities when present therein as a result of application of amicarbazone to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Alfalfa, forage	0.05
Alfalfa, hay	0.10
Cotton, gin byproducts	0.30
Cotton, undelinted seed	0.07
Soybean, forage	1.50
Soybean, hay	5.0
Soybean, seed	0.80
Wheat, forage	0.50
Wheat, grain	0.10
Wheat, grain, milled by-products	0.15
Wheat, hay	1.0
Wheat, straw	0.50

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0267; FRL–7738–6]

Pyridaben; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyridaben in or on hop, dried cones; papaya; star apple; sapote, black; mango; sapodilla; sapote, mamey; canistel, fruit, stone, group 12; strawberry; and tomato. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain pyridaben tolerances that are no longer needed as result of this action.

DATES: This regulation is effective September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0267. 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, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/.*

II. Background and Statutory Findings

In the **Federal Register** of July 3, 2003 (68 FR 39942) (FRL–7315–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (0E6068, 1E6226, 1E6303, 2E6457, and 2E6460) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The