Dated: August 19, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.554, the table in paragraph (b) is amended by alphabetically adding commodities to read as follows:

§ 180.544 Methoxyfenozide; tolerance for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
sorghum, grain	0.05	12/31/2007
sorghum, grain, forage	15	12/31/2007
sorghum, grain, stover	125	12/31/2007

* * * * *

[FR Doc. 05–17131 Filed 8–30–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0217; FRL–7731–6]

Flonicamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of flonicamid and its metabolites in or on certain plant and livestock commodities. ISK Biosciences 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 August 31, 2005. Objections and requests for hearings must be received on or before October 31, 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–2005–0217. 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: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail address:*sibold.ann@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 May 23, 2003 (68 FR 28218) (FRL–7307–5), 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 3F6552) by ISK Biosciences, 7470 Auburn Road, suite A, Concord, Ohio 44077. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for the combined residues of the insecticide flonicamid, [*N*-(cyanomethyl)-4-trifluoromethylnicotinamide] and its metabolites, TFNA, (4-trifluoromethylnicotinic acid), TFNA-AM, (4-trifluoromethylnicotinamide) and TFNG, [*N*-(4-trifluoromethylnicotinoyl)glycine] in or on the raw agricultural commodities: Celery, at 1.2 parts per million (ppm); cotton, at 0.5 ppm; cotton, gin trash, at 6.0 ppm; cotton, hulls, at 1.0 ppm; cotton, meal, at 1.0 ppm; fruit, pome, group 11, at 0.2 ppm; fruit, stone, group 12, except plum and fresh prune plum, at 0.7 ppm; lettuce, head, at 1.0 ppm; lettuce, leaf, at 4.0 ppm; plum, at 0.1 ppm; potato, at 0.2 ppm; potato, flakes, at 0.4 ppm; prune, fresh, at 0.1; spinach, at 9.0 ppm; tomato, paste, at 2.0 ppm; tomato, puree, at 0.5 ppm; vegetable,

cucurbit, group 9, at 0.4 ppm; vegetable, fruiting, group 8, at 0.4 ppm; by establishing tolerances for the combined residues of the insecticide flonicamid, [*N*-(cyanomethyl)-4-trifluoromethylnicotinamide] and its metabolite TFNA-AM, (4-trifluoromethylnicotinamide) in animal tissues and poultry meat byproducts:Cattle, fat, at 0.01 ppm; cattle, meat, at 0.04 ppm; eggs, at 0.02 ppm; goat, fat, at 0.01 ppm; goat, meat, at 0.04 ppm; hog, fat, at 0.01; hog, meat, at 0.01 ppm; horse, fat, at 0.01 ppm; horse, meat, at 0.04 ppm; milk, at 0.02 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, meat byproducts, at 0.01 ppm; sheep, fat, at 0.01 ppm; sheep, meat, at 0.04 ppm; by establishing tolerances for the combined residues of the insecticide flonicamid [*N*-(cyanomethyl)-4-trifluoromethylnicotinamide] and its metabolites TFNA, (4-trifluoromethylnicotinic acid) and TFNA-AM, (4-trifluoromethylnicotinamide) in the animal meat byproducts: cattle, meat byproducts, at 0.06 ppm; goat, meat byproducts, at 0.06 ppm; hog, meat byproducts, at 0.01 ppm; horse, meat byproducts, at 0.06 ppm; and sheep, meat byproducts, at 0.06 ppm. That notice included a summary of the petition prepared by ISK Biosciences, the registrant. One comment was received on the notice of filing. EPA's response to this comment is discussed 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 flonicamid and its metabolites on various crop and livestock commodities at levels set forth in the list below.

Tolerances for combined residues of flonicamid and its metabolites in/on crops and livestock commodities.

1. Recommended tolerances for combined residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in/on crops.

Cotton, undelinted seed at 0.50 ppm
Cotton, gin byproducts at 6.0 ppm
Cotton, hulls at 2.0 ppm
Cotton, meal at 1.0 ppm
Fruit, pome, group 11 at 0.20 ppm
Fruit, stone, group at 12 0.60 ppm
Potato 0.20 at ppm
Potato, granular/flakes at 0.40 ppm
Spinach at 9.0 ppm
Tomato, paste at 2.0 ppm
Tomato, puree at 0.50 ppm
Vegetable, cucurbit, group at 0.40 ppm
Vegetable, fruiting, group at 0.40 ppm
Vegetable, leafy except Brassica group 4, except spinach at 4.0 ppm

2. Recommended tolerances for combined residues of flonicamid and its metabolites TFNA and TFNA-AM in/on livestock commodities.

Cattle, fat at 0.02 ppm
Cattle, meat at 0.05 ppm
Egg at 0.03 ppm
Goat, fat at 0.02 ppm
Goat, meat at 0.05 ppm
Horse, fat at 0.02 ppm
Horse, meat at 0.05 ppm
Milk at 0.02 ppm
Poultry, fat at 0.02 ppm
Poultry, meat at 0.02 ppm
Poultry, meat byproducts at 0.02 ppm
Sheep, fat at 0.02 ppm
Sheep, meat at 0.05 ppm
Cattle, meat byproducts at 0.08 ppm
Goat, meat byproducts at 0.08 ppm
Horse, meat byproducts at 0.08 ppm
Sheep, meat byproducts at 0.08 ppm

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by flonicamid as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies are discussed in Table 1 of this unit.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY OF FLONICAMID

Guideline No.	Study Type	Dose Levels	Results
870.3100	90–Day oral toxicity rodents (rats) 28–day range-finding	0, 50 (males), 200, 1,000,2,000 (males), or 5,000(females) ppm (3.08, 12.11,60.0, or 119.4 mg/kg/day,males and 14.52, 72.3, or340.1 mg/kg/day, females) 0, 50 (males), 100, 500, 1,000,5,000 or 10,000 (females)ppm (3.61, 7.47, 36.45,73.8, or 353.4 mg/kg/day,males and 8.36, 41.24, 81.9,372.6, or 642 mg/kg/day,females)	NOAEL is 200 ppm (12.11 mg/kg/day) formales and 1,000 ppm (72.3 mg/kg/day) forfemales LOAELs were 1,000 ppm (60.0 mg/kg/day) formales based on changes in the kidney (hyalinedeposition) and 5,000 ppm (340 mg/kg/day) forfemales based on kidney (hyaline deposition)and liver changes (centrilobular hypertrophy) NOAEL is 100 ppm (7.47 mg/kg/day) for malesand 1,000 ppm (81.9 mg/kg/day) for females. LOAELs were 500 ppm (36.45 mg/kg/day) formales based on changes in the kidney (hyalinedeposition) and 5,000 ppm for females (372.6mg/kg/day) based on kidney (hyalinedeposition), liver changes (centrilobularhypertrophy), hematological effects (anemia)and clinical chemistry (increased cholesterol)
870.3100	90–Day oral toxicity rodents (mice)	0, 100, 1,000 or 7,000 ppm(0, 15.25, 153.9 or 1,069mg/kg bw/day in males,and 0, 20.10, 191.5, or 1,248mg/kg bw/day in females)	NOAEL is 100 ppm (males: 15.25 mg/kgbw/day, females: 20.10 mg/kg bw/day) LOAEL is 1,000 ppm in (males: 153.9 mg/kgbw/day; females: 191.5 mg/kg bw/day) basedon extramedullary hematopoiesis of the spleen Many of the tissues/organs recommended byGuideline 870.3100 were not histologicallyexamined in any dose group, but this study isnot required and serves as a range-findingstudy for the mouse carcinogenicity study.Therefore, it is classified as acceptable, non-guideline study
870.3150	90–Day oral toxicity (nonrodents- dogs)	0, 3, 8, 20, or 50 (females) mg/kg bw/day	NOAEL is 8 mg/kg/day in males and 20 mg/kg/day for female LOAEL is 20 mg/kg/day in males and 50 mg/kg/day in females, based on acute clinical signs in males and females (vomiting, first observed on Day 1 and last observed on Day 90), clinical pathology at 7 weeks (increased total protein levels in males, lower red blood cells and higher reticulocytescounts in females), increased adrenal weights in males, decreased thymusgland weights in males, and increased kidney tubular vacuolation infemales at study termination
870.3200	28–Day dermal toxicity (rats)	0, 20, 150, or 1,000 mg/kg/day	NOAEL is 1,000 mg/kg/day LOAEL is >1,000 mg/kg/day
870.3700	Prenatal developmental toxicity (rats)	0, 20, 100 or 500 mg/kg bw/day	Maternal NOAEL is 100 mg/kg bw/day LOAEL is 500 mg/kg bw/day, based onincreased liver weight, and liver and kidneypathological changes (hypertrophy ofcentrilobular hepatocytes in liver andvacuolation of proximal tubular cell inkidneys) Developmental NOAEL is 100 mg/kg bw/day LOAEL is 500 mg/kg bw/day, based on the increased incidence of cervical rib

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

Guideline No.	Study Type	Dose Levels	Results
870.3700	Prenatal developmentaltoxicity (rabbits)	0, 2.5, 7.5, or 25 mg/kg/day	Maternal NOAEL is 7.5 mg/kg/day LOAEL is 25 mg/kg, based on decreased bodyweights, body weight gains, and food consumption Developmental NOAEL is ≥ 25 mg/kg/day LOAEL is not established
870.3800	Reproduction and fertility effects (rats)	0, 50, 300, or 1,800 ppm(0/0, 3.7/4.4, 22.3/26.5, and132.9/153.4 mg/kg bw/day [M/F]	Parental NOAEL is 50 ppm (equivalent to 3.7/4.4mg/kg/day [M/F] LOAEL is 300 ppm (equivalent to 22.3/26.5mg/kg/day [M/F] based on increased relativekidney weight and hyaline droplet depositionin the proximal tubules of the kidneys in themales and increased blood serum LH levels inthe F1 females Offspring NOAEL is 300 ppm (equivalent to 22.3/26.5mg/kg/day [M/F]. LOAEL is 1,800 ppm(equivalent to 132.9/153.4 mg/kg/day [M/F]based on decreased absolute and relative tobody uterus weights and delayed sexualmaturation in the F1 females Reproductive Performance NOAEL is 1,800 ppm (equivalent to 132.9/153.4mg/kg/day [M/F] LOAEL for reproductive performance was notobserved
870.4100	Chronic toxicity (dogs)	0, 3, 8, or 20 mg/kg/day	NOAEL is 8 mg/kg/day LOAEL is 20 mg/kg/day, based on acute clinical signs(vomiting, mostly within the first week), clinical pathology at 12 months (higher reticulocytes counts) in males and females
870.4200	Carcinogenicity (mice)	0, 250, 750, or 2250 ppm(0/0, 29/38, 88/112, or261/334 mg/kg/day [M/F]	NOAEL was not established LOAEL is 250 ppm (equivalent to 29/38mg/kg/day [M/F]), based on minimal tomoderate centrilobular hepatocellularhypertrophy, minimal to severeextramedullary hematopoiesis, minimal tomoderate pigment deposition in the sternalbone marrow, and increased incidence of tissuemasses/nodules in the lungs in the males, andminimal to moderate decreased cellularity inthe femoral bone marrow andhyperplasia/hypertrophy of the epithelial cellsof the terminal bronchioles of the females At the doses tested, the carcinogenic potentialof IKI-220 (flonicamid) is positive at 250 ppmin males and females based on the increasedincidence of alveolar/bronchiolar adenomas,carcinomas, and combinedadenomas/carcinomas. Dosing was consideredadequate based on increased incidence of tissuemasses/nodules in the lungs and microscopicfindings in the liver, spleen, bone marrow, andlungs. However, data were providedsuggesting this effect is specific to sensitivestrains of mice Carcinogenic in mice

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

Guideline No.	Study Type	Dose Levels	Results
870.4200	Carcinogenicity (mice)	0, 10, 25, 80, 250 ppmmales: 0, 1.20, 3.14, 10.0,30.3 mg/kg/day; females: 0,1.42, 3.67, 11.8, 36.3 mg/kg/day	NOAEL is 80 ppm (equivalent to 10/12mg/kg/day in males/females) LOAEL is 250 ppm (equivalent to 30/36mg/kg/day in males/females) based on lungmasses and terminal bronchiole epithelial cellhyperplasia/hypertrophy in both sexes At the doses tested, the carcinogenic potentialof IKI-220 (flonicamid) is positive in males andfemales based on the incidences ofalveolar/bronchiolar adenomas, carcinomas,and combined adenomas and/or carcinomas. Dosing was consideredadequate based on lung masses and terminal bronchiole epithelialcell hyperplasia/hypertrophy in both sexes Carcinogenic in mice
870.4300	Combined Chronic/carcinogenicity (rats)	0, 50 (males), 100 (males),200, 1,000, or 5,000 (females) ppm (0/0, 1.84,3.68, 7.32/8.92, 36.5/44.1, and 219 mg/kg/day [M/F]	NOAEL is 200 ppm (equivalent to 7.32/8.92mg/kg/day in males/females) LOAEL is 1,000 ppm (equivalent to 36.5/44.1mg/kg/day in males/females) based ondecreased body weights and body weight gains,and increased incidences of keratitis in malesand striated muscle fiber atrophy in females At the high dose there was an incidence (12%)of nasolacrimal duct squamous cell carcinomasslightly outside the historical control range (0-10%) in male rats. A correlation between theincidence of inflammation and the fluctuatingincidence of nasal tumors was made acrossdose groups. EPA did not consider thenasolacrimal duct tumors to be treatment-related Female rats had a significant increasing trendin nasolacrimal duct squamous cell carcinomasat <0.05, and at the high dose was slightlyabove the historical control mean (0.8%) andrange (0-4%). EPA considered the nasolacrimal duct squamouscell carcinomas to be possibly treatment related, but that a clearassociation with treatment could not be made
870.5100	Bacterial reverse mutation	61.7 to 5,000 μg/plate +/-S9	Negative
870.5100	Bacterial system, mammalian activationgene mutation	33 to 5,000 μg/plate +/-S9	Negative for metabolite TFNA
870.5100	Bacterial system, mammalian activationgene mutation	33 to 5,000 ug/plate +/-S9	Negative for metabolite TFNA-AM
870.5100	Bacterial system, mammalian activationgene mutation	33 to 5,000 ug/plate +/-S9	Negative for metabolite TFNG-AM
870.5100	Bacterial system, mammalian activationgene mutation	33 to 5,000 μg/plate +/-S9	Negative for metabolite TFNA-OH
870.5100	Bacterial system,mammalian activation gene mutation	5 to 5000 ug/plate +/-S9	Negative for metabolite TFNG

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

Guideline No.	Study Type	Dose Levels	Results
870.5300	In vitro mammalian cellgene mutation	28.3 to 2,290 μg/mL initialtest, and 143 to 2,290μg/mL repeat	Negative
870.5375	*In vitro* Cytogenetics	573, 1145 and 2290 μg/mL	Negative
870.5395	*In vivo* cyto-genet-ic(micronucleus) test in mice	Twice orally by intragastricgavage at doses of 250, 500and 1,000 mg/kg/day formales and 125, 250 and 500mg/kg/day for females	Negative
Non-guideline	Other genotoxicity, *in vivo* Comet assay	Single doses of 375, 750 and 1,500 mg/kg	Was not positive for nuclear migration up to1,500 mg/kg
Non-guideline	Unscheduled DNA synthesis	Once orally at 600 and 2,000 mg/kg	Is not genotoxic in hepatocytes from treated rats
870.6200	Acute neurotoxicityscreening battery (rats)	0, 100, 300, 600 (males), or 1,000 mg/kg/day	NOAEL is 600 mg/kg in males and 300 mg/kgin females LOAEL is 1,000 mg/kg based on mortality andsigns of toxicity (decreased motor activity,tremors, impaired respiration, and impairedgait) in males This acute neurotoxicity study is unacceptablebecause interval motor activity data were notprovided as specified according to guidelines,FOB handling and open-field observationswere incomplete, and positive data providedwere from a lab other than the performing labfor this study. This study is not required forthis risk assessment and additional informationis not required
870.6200	Subchronic neurotoxicity screeningbattery (rats)	0, 200, 1000, or 10,000 ppm(0/0, 13/16, 67/81, or625/722 mg/kg/day [M/F]	NOAEL is 200/1,000 ppm (equivalent to 13/81mg/kg/day [M/F] LOAEL is 1,000/10,000 ppm (equivalent to67/722 mg/kg/day [M/F] based on decreasedmotor activity, rearing, and foot splay inmales, decreased body weights, body weightgains, and food consumption in males andfemales
870.7485	Metabolism andpharmacokinetics (rats)	Pilot excretion study, singleoral dose 0.85 or 21 mg/kgand pilot pharmacokineticstudy, single oral dose of 2or 50 mg/kg	IKI-220 (flonicamid) was rapidly absorbed andexcreted with no apparent differences betweenthe sexes. By 48 hours after treatment, 93%of the administered dose had been eliminatedand by 168 hours ~96% was eliminated. Theprimary route of elimination was the urine,accounting for ~90% of the dose. The feces oftreated rats accounted for ~5% of theadministered dose, with no significant amountsof radiolabel detected in expired air of eithersex. After 168 hours of a single high or lowdose of the test material, <3% of theradioactivity was recovered in the carcass and<0.05% in the blood, irrespective of dose orsex The pharmacokinetic parameters were alsosimilar between the dose levels (2 and 50mg/kg) and sexes. The radiolabel was rapidlyabsorbed and excreted. The apparent plasmahalf-life (T½) was 4.8-6.0 hours and theelimination followed first order kinetics. Thetime of maximum plasma concentration(Tmax) for individual animals ranged from0.25 to 1 hour after treatment (with a mean foreach group of 0.3-0.6 hours)

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

Guideline No.	Study Type	Dose Levels	Results
870.7485	Metabolism and pharmacokinetics (rats)	2 or 400 mg/kg	Appears that the overall recovery ofradioactive dose from all group was 94-99% by168 hours post-dose. Absorption was rapidand extensive, detected in plasma within 10minutes of dosing, with maximum plasmaconcentrations within 24-54 minutes. By 168hours post-dose, total urinary excretion was72-78%, cage rinse was 10-21%, and fecalexcretion was 4-7% dose. Parent (IKI-220)(flonicamid) and 9 metabolites accounted for80-94% of the dose for all groups. Parent wasdetected primarily in the urine, 46-73% of thedose in excreta in all groups. The primarymetabolite was 4-trifluoromethylnicotinamide(TFNA-AM), 18-27% dose in all dose groups,along with minor amounts of TFNA-AM N-oxide (1-4% dose).Other metabolites in urine and feces were detected atless than or equal to 2.5% of the dose.IKI-220 (flonicamid) was excreted primarily unchangedin the urine, but biotransformation of IKI-220(flonicamid) in rats included nitrile hydrolysis,N-oxidation, hydroxylation of the pyridine ring and amidehydrolysis

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional safety 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 exposure (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

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

TABLE 2.—TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLONICAMID HUMAN HEALTH RISK ASSESSMENTS

Exposure Scenario	Dose Used in RiskAssessment, UF	Special FQPA SF* andLevel of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary	None	FQPA SF = NA aPAD = NA	Quantitative risk assessment is notrequired since there are no acute dietarytoxicity concerns

TABLE 2.—TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLONICAMID HUMAN HEALTH RISK ASSESSMENTS—Continued

Exposure Scenario	Dose Used in RiskAssessment, UF	Special FQPA SF* andLevel of Concern for Risk Assessment	Study and Toxicological Effects
Chronic dietary	NOAEL = 3.7 mg/kg/day UF = 100 Chronic RfD = 0.04mg/kg/day	FQPA SF = 1 aPAD = chronic RfD/ FQPA SF= 0.04 mg/kg/day	2–Generation Reproduction rat Parental LOAEL = 22 mg/kg/day basedon increased kidney weights, kidney hyaline deposition, increased blood serum LH (F1 females)
Cancer	Suggestive evidence of carcinogenic potential		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances are being proposed for the combined residues of flonicamid and its metabolites, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from flonicamid and its metabolites in food as follows:

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

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™ Version 2), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% crop treated, tolerance level residues, and drinking water estimated concentration of 0.94 parts per billion (ppb).

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS to estimate pesticide concentrations (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

In order to fully implement the requirements of FQPA, EPA determined that chronic estimated drinking water concentrations (EDWCs) can be used directly in chronic dietary exposure assessments to calculate aggregate dietary (food + water) risk. This is done by using the relevant PRZM-EXAMS value as a residue for water (all sources) in the dietary exposure assessment. The principal advantage of this approach is that the actual individual body weight and water consumption data from the CSFII are used, rather than assumed weights and consumption for broad age groups. This refinement has been used for the flonicamid chronic aggregate risk assessment for surface water.

Based on the PRZM/EXAMS and SCI-GROW models, the EDWCs of combined residues of flonicamid and its metabolites for chronic exposures are estimated to be 0.94 ppb for surface water and 0.00137 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).

Flonicamid 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 flonicamid and any other substances, and flonicamid does not appear to produce a toxic metabolite produced by other substances. EPA considered that there might be a common mechanism among flonicamid and other pesticides. EPA concluded that the evidence did not support a finding of common mechanism for flonicamid and other pesticides. For the purposes of this tolerance action, therefore, EPA has not assumed that flonicamid 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 was no evidence for quantitative or qualitative susceptibility following oral or dermal exposures to rats *in utero* or oral exposure to rabbits *in utero.* Following oral exposures to rats, developmental effects were seen only in the presence of maternal toxicity. No developmental effects were seen in rabbits.

The degree of concern for prenatal and/or postnatal susceptibility is low due to the lack of evidence of qualitative and quantitative susceptibility. This is because developmental effects were only seen in one species, only at the maternal toxicity dose, and effects seen in offspring were not more severe than those seen in the maternal toxicity. Thus, neither qualitative nor quantitative susceptibility issues are of concern for flonicamid. The database for required developmental and reproductive studies is complete, thus there are no residual uncertainties.

3. *Conclusion.* The FQPA Safety Factor is reduced to 1X because:

i. There is a complete toxicity database;

ii. There is a lack of susceptibility evidence in the developmental studies and reproductive study (The effects seen in offspring were mild and occurred only in one species.);

iii. The dietary food exposure assessment utilizes proposed tolerance level or higher residues and 100% CT information for all commodities; and

iv. The dietary drinking water assessment (Tier 1 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* No acute risk is expected for the following reasons: No acute toxicity endpoint was identified. There was no endpoint noted in the database from a single dose exposure that could be used for risk assessment. This included the acute neurotoxicity and developmental toxicity studies as well as other short- and long-term studies. Body weight decreases were consider inappropriate for this acute endpoint since in these studies they occur later then the acute time interval. The observed vomiting in either the acute or subchronic dog studies occurred without manifestations of any other acute clinical signs or related pathology. Thus acute clinical effects seen in the dog studies were considered not appropriate. The acute neurotoxicity study was also not appropriate for the general population since the effects observed only occurred in the high doses tested where mortality was also observed, and therefore the neurotoxicity signs were probably part of the death response. While death can be an acute response, the dose at which death occurred was in EPA's judgement, so high that it is unlikely to happen. In addition, the acute neurotoxicity study did not have all the required observations. The effects observed in the developmental studies were not attributable to an acute response, and therefore the developmental studies were not used for an acute endpoint for females of reproductive age. Thus, an acute dietary endpoint was not considered appropriate.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flonicamid and its metabolites from food and drinking water will utilize 11% of the cPAD for the U.S. population, 15% of the cPAD for all infants <1 year old, and 25% of the cPAD for children 1-2 years old. There are no residential uses for flonicamid that result in chronic residential exposure to flonicamid.

3. *Short-term and intermediate 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). Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* In assessing the carcinogenic potential of flonicamid, EPA took into account the following weight-of-the-evidence considerations:

i. Flonicamid is not mutagenic.

ii. The treatment-related CD-1 mouse lung tumors (benign and malignant) which occurred in both sexes were due to an established mitogenic mode of action that occurred in a susceptible mouse strain with a high background. A clear species difference was observed between mice and rats in the incidence of lung tumors and the BrdU Index studies. (Bromodeoxyuridine (BrdU) Index studies are used to quantify rates of cell proliferation). No tumors were seen in the lungs of rats. The flonicamid induced increase in the BrdU Index appears to be related to the different sensitivity of strains of mice, with the CD-1 mice being a relatively sensitive strain.

iii. The only other tumor response was nasolacrimal duct tumors which occurred in female rats at the high dose which were considered to be possibly treatment-related, but a clear association with treatment could not be made. Unlike male rats, the nasal tumor response in females could not be clearly associated with spontaneous inflammation related to malocclusion of incisor teeth, due to the low incidence of both the neoplastic and non-neoplastic lesions. Given these findings in the cancer and mutagenicity studies, EPA regards the carcinogenic potential of flonicamid as very low and concludes that it poses no greater than a negligible cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available to enforce the proposed tolerances of flonicamid and the major metabolites in plants and livestock. The proposed method for plants uses a LC/MS/MS (FMC No. P-3561M) to determine the residues of flonicamid and its major metabolites, TFNA-AM (4-trifluoromethylnicotinamide), TFNA (4-trifluoromethylnicotinic acid), and TFNG [*N*-(4-trifluoromethylnicotinoyl)glycine]. The reported LOQ was 0.01 ppm and the reported LOD was 0.005 ppm for peach, potato, processed commodities of apples, plums, potatoes, and tomatoes. The reported LOQ was 0.02 ppm and the LOD was 0.01 ppm for each analyte in/on wheat; cotton seed, hulls, and refined oil. The method was adequately validated by an independent laboratory.

For livestock, three methods were proposed: LC/MS/MS method (RCC No. 844743) for residues in eggs and livestock tissues, LC/MS method (RCC No. 842993) for residues in milk, and LC/MS/MS method (FMC P3580) which include an acid hydrolysis step for residues in cattle muscle, kidney and liver. The three livestock methods recommend the use of calibration standards, prepared by using control matrix extracts for all or some of the analyze/matrix combinations to remove matrix enhancement effects. The methods were adequately validated by an independent laboratory. These methods may be used for the determination of residues of flonicamid and its metabolites TFNA-AM, TFNG, and TFNA. The validated LOQ was 0.01 ppm and LOD was 0.005 ppm for methods 844743 and 842993; the reported validated LOQ was 0.025 ppm and the LOD was 0.005 ppm for method FMC P3580.

Enforcement methodology 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, Mexican or Canadian MRLs or tolerances have been established. Therefore no compatibility questions exist with respect to Codex.

C. Response to Comments

EPA received one comment from the National Cotton Council, which stated that it supports ISK Bioscience's request for the establishment of tolerances in the listed food and feed items. In today's action, EPA is responding affirmatively to this comment.

V. Conclusion

Therefore, tolerances are established for the combined residues of flonicamid [*N*-(cyanomethyl)-4-trifluoromethyl)-3-pyridinecarboxamide], and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] and TFNG [*N*-(4-trifluoromethylnicotinoyl)glycine] in or on the crops at tolerance levels listed in Unit III.

Tolerances are established for the combined residues of flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide], and its metabolites TFNA [4-trifluoromethylnicotinic acid] and TFNA-AM [4-trifluoromethylnicotinamide] in or on the livestock commodities at tolerance levels listed in Unit III.

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–2005–0217 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 October 31, 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 VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0217, 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: August 19, 2005.

Lois A. Rossi,

Acting 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 180.613 is added to read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [*N*-(4-trifluoromethylnicotinoyl)glycine] in or on the following raw agricultural commodities:

Commodity	Parts per million
Cotton, gin byproducts	6.0
Cotton, hulls	2.0
Cotton, meal	1.0
Cotton, undelinted seed	0.50
Fruit, pome, group 11	0.20
Fruit, stone, group 12	0.60
Potato	0.20
Potato, granular/flakes	0.40
Spinach	9.0
Tomato, paste	2.0
Tomato, puree	0.50
Vegetable, cucurbit, group	0.40
Vegetable, fruiting, group	0.40

Commodity	Parts per million
Vegetable, leafy except Brassica group 4, except spinach	4.0

(2) Tolerances are established for combined residues of flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide], and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.05
Cattle, meat by-products	0.08
Egg	0.03
Goat, fat	0.02
Goat, meat	0.05
Goat, meat byproducts	0.08
Horse, fat	0.02
Horse, meat	0.05
Horse, meat by-products	0.08
Milk	0.02
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat by-products	0.02
Sheep, fat	0.02
Sheep, meat	0.05
Sheep, meat by products	0.08

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

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

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

[FR Doc. 05–17128 Filed 8–30–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0165; FRL–7719–8]

Halosulfuron-methyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of halosulfuron-methyl in or on sweet potatoes. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sweet potatoes. This regulation establishes a maximum permissible level for residues of halosulfuron-methyl in this food commodity. The tolerance will expire and is revoked on December 31, 2008.

DATES: This regulation is effective August 31, 2005. Objections and requests for hearings must be received on or before October 31, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2005–0165. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather 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 on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide halosulfuron-methyl, in or on sweet potatoes at 1.0 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2008. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related tolerances to set binding precedents for the application of section 408 of FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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.''