significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. Because this rule merely removes regulatory provisions made obsolete by statute, prior notice and comment and a delayed effective date are unnecessary and contrary to the public interest. 5 U.S.C. 553(b)(B) and (d)(3). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply.

Drafting Information

The principal author of this Treasury decision is Jamie J. Kim of the Office of Associate Chief Counsel (Income Tax and Accounting), IRS.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Removal of Temporary Regulation

■ Accordingly, 26 CFR Part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.463–1T [Removed]

■ **Par. 2.** Section 1.463–1T is removed.

Approved: July 7, 2004.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Gregory F. Jenner,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 04–16090 Filed 7–15–04; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[AD–FRL–7788–7]

RIN 2060–AK28

Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Routine Maintenance, Repair and Replacement; Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public hearing.

SUMMARY: The EPA is announcing a public hearing to be held on August 2, 2004, regarding the July 1, 2004 reconsideration notice for regulations governing the NSR programs mandated by parts C and D of title I of the Clean Air Act (CAA). See 69 FR 40278. Being reconsidered are parts of the NSR regulations for routine maintenance, repair and replacement (RMRR) that were promulgated on October 27, 2003. See 68 FR 61249. The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the July 1, 2004 document.

DATES: The public hearing will convene on August 2, 2004 at 9 a.m. eastern daylight time and will end at 5 p.m. eastern daylight time or when the last registered speaker has had an opportunity to speak.

ADDRESSES: The public hearing will be held at the Sheraton Imperial Hotel, 4700 Emperor Boulevard, Durham, North Carolina 27703; telephone (919) 941–5050.

Docket: Documents related to this rule are available for public inspection in the EPA Docket Center under E-Docket ID No. OAR–2002–0068 (Legacy Docket ID No. A–2002–04). The record for this public hearing will remain open until September 1, 2004, to allow 30 days for submittal of additional information related to the hearing.

FOR FURTHER INFORMATION CONTACT: *Mr. Dave Svendsgaard* at (919) 541–2380, telefax (919) 541–5509, E-mail: *svendsgaard.dave@epa.gov,* or by mail at U.S. Environmental Protection Agency, OAQPS, Information Transfer and Program Integration Division, (C339–03), Research Triangle Park, North Carolina 27711. If you would like to speak at the hearing, you should contact *Ms. Chandra Kennedy*, U.S., Environmental Protection Agency, OAQPS, Information Transfer and Program Integration Division, (C339–03), Research Triangle Park, North Carolina 27711; telephone (919) 541–5319 or E-mail *kennedy.chandra@epa.gov*, by July 19, 2004, to confirm a reservation to speak. We will notify speakers of their assigned times by July 26, 2004. We will continue to accommodate requests to speak that are received after the July 19, 2004, deadline, subject to available time slots. Presentations will be limited to 5 minutes each.

SUPPLEMENTARY INFORMATION: The EPA's planned seating arrangement for the hearing is theater style, with seating available on a first-come, first-served basis for about 250 people. An agenda will be provided at the hearing.

Dated: July 8, 2004.

Gregory A. Green,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 04–16329 Filed 7–15–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0120; FRL–7367–1]

Spiroxamine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of spiroxamine in or on grape, banana, and hop, dried cones. Bayer CropScience and the Interregional Research Project Number 4 (IR-4), respectively, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 16, 2004. Objections and requests for hearings must be received on or before September 14, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0120. 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. 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:

(703) 305–7610; e-mail address:*jackson.sidney@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. 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. 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. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of March 7, 2003 (68 FR 11088) (FRL–7290–5), and December 10, 2003 (68 FR 68904) (FRL–7337–6), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0F6122, 3E6538, and 3E6783) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709, and (PP 3E6518) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390, respectively. These notices included a summary of the petitions prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine, and its metabolites containing the N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane moiety (formerly known as the aminodiol moiety), in or on grape at 1.0 parts per million (ppm), and grape, raisin at 1.3 ppm (PP 0F6122); banana at 3.0 ppm (3E6538); hop, dried cones (import) at 50 ppm (3E6783); and hop (United States) at 11 ppm (3E6518). Subsequently, PP 0F6122 has been amended to delete grape, raisin at 1.3 ppm, and PP 3E6518 has been amended to increase the tolerance level for ''hop at 11 ppm'' to ''hop, dried cones at 50 ppm.''

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of these actions. 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 import tolerances for combined residues of spiroxamine on grape at 1.0 ppm, banana at 3.0 ppm, and hop, dried cones at 50 ppm (import and U.S. grown). EPA's assessment of exposures and risks associated with establishing these tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by spiroxamine is 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.

Subchronic studies show the target organ of spiroxamine toxicity is the liver. Subchronic studies were characterized by slight to mild hepatotoxicity, with associated elevation in liver enzymes. Mucous membranes of the esophagus and forestomach were keratinized and hyperplastic due to the strong irritant properties of spiroxamine. Long-term administration of spiroxamine in the dog resulted in hepatocytomegaly, cataracts, and liver discoloration. In the rat, it resulted in an increased mortality in females, decreased body weights and body weight gains in both sexes, and increased esophageal hyperkeratosis in both sexes, while in the mouse, chronic administration resulted in uterine nodules, hyperplasia in the adrenal gland of males, hyperkeratosis in the esophagus, forestomach, and tongue of females, and acanthosis in the pinnae and tails of females. In rats, developmental effects entailed delayed ossification. Developmental effects were not seen in rabbits. There was no evidence of increased susceptibility of the young animals following exposure to spiroxamine in any developmental toxicity studies in the data base. There was evidence of mild spiroxamine-induced neurotoxicity characterized by

piloerection and slight to moderate gait incoordination, and functional observational battery (FOB) effects of decreased forelimb grip strength and foot splay in males in the acute neurotoxicity study. No neuropathology was seen in either the acute or subchronic toxicity studies in rats and no neurotoxicity was detected in the subchronic study. Spiroxamine has no carcinogenic potential, as indicated in both the rat and the mouse carcinogenicity studies. In addition, spiroxamine has no mutagenicity potential, based on several *in vivo* and *in vitro* studies.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity--rodents (rats) active ingredient (a.i.)	NOAEL = M: 9.3, F: 13.2 mg/kg/day LOAEL = M: 54.9, F: 75.1 mg/kg/day based on decreased body weights and body weight gains in both sexes, hyperkeratosis and hyperplasia/hypertrophy in the esophagus of both sexes and hyperkeratosis in the forestomach of males. Minimal to marked hyperkeratosis in the tongue of both sexes. Slight multifocal hyperplasia in the urinary bladder of both sexes. Minimal to slight hyaline droplet degeneration in the liver in males.
870.3100	90–Day oral toxicity rodents (rats) Metabolite KWG 4168 N-oxide	NOAEL = M: 8.8, F: 9.7 mg/kg/day LOAEL = M: 45.0, F: 53.6 mg/kg/day based on hyperkeratosis in the esophagus and forestomach
870.3150	90–Day oral toxicity--nonrodents (dogs)	NOAEL = M: 16.19, F: 15.05 mg/kg/day LOAEL = M: 20.02, F: 21.29 mg/kg/day based on decreased albumin in females, increased absolute and relative liver weights in males, and increased diffuse hepatocytomegaly in males
870.3200	21/28–Day dermal toxicity (rabbit)	NOAEL = 0.2 mg/kg/day LOAEL = 0.5 mg/kg/day based on erythema at the application site
870.3465	28–Day inhalation toxicity (rats)	NOAEL = 23.6 mg/kg/day (0.087 mg/L) LOAEL = 140.5 mg/kg/day (0.518 mg/L) based on decreased body weights and body weight gains, increased incidences of clinical signs of toxicity and dermal irritation, thymic atrophy, and toxicity to the skin, respiratory system, and liver
870.3700	Prenatal (oral) developmental-rodents (rats)	*Maternal* NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weights, body weight gains, and food consumption *Developmental* NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on increased incidence of delayed skeletal development (incomplete ossification) of the os interparietal (fetal and litter incidences) and os parietale (fetal incidences)

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

Guideline No.	Study Type	Results
870.3700	Prenatal (dermal) developmental--rodents (rats)	*Maternal (Systemic)* NOAEL = 5 mg/kg/day LOAEL = 10 mg/kg/day based on decreased body weight gains *Maternal (Dermal)* NOAEL = less than 5 mg/kg/day LOAEL (Dermal) = 5 mg/kg/day based on very slight erythema and/or slight scaling of skin *Developmental* NOAEL = 20 mg/kg/day LOAEL = 80 mg/kg/day based on the increased fetal and litter incidence of incomplete/non-ossification of the os occipital and the increased non-ossification of the left distal phalanx of digit number 4 of the forelimb
870.3700	Prenatal developmental in nonrodents (rabbits)	*Maternal* NOAEL = 20 mg/kg/day LOAEL = 80 mg/kg/day based on mortality, clinical signs of toxicity (encrusted mouth, anal prolapse, and little/soft feces), decreased body weight gains, and decreased food consumption *Developmental* NOAEL = 80 mg/kg/day LOAEL: Not Achieved
870.3800	Reproduction and fertility effects (rats)	*Parental/Systemic* NOAEL = M: 2.5, F: 2.7 mg/kg/day LOAEL = M: 10.8, F: 11.9 mg/kg/day based on decreased food consumption during lactation and on increased incidences of esophageal hyperkeratosis in females *Reproductive* NOAEL = M: 44.8, F: 48.8 mg/kg/day LOAEL = Not achieved *Offspring* NOAEL = M: 10.8, F: 11.9 mg/kg/day LOAEL = M: 44.8, F: 48.8 mg/kg/day based on decreased litter size and pup weight and increased clinical signs of toxicity in the F1 generation
870.4100	Chronic toxicity--dogs	NOAEL = M: 2.47, F: 2.48 mg/kg/day LOAEL = M: 28.03, F: 25.84 mg/kg/day based on hepato/cytomegaly, cataracts, and decreased albumin in males and females; liver discoloration and decreased triglycerides in females; and increased alanine aminotransferase in males
870.4200	Carcinogenicity--rats	NOAEL = M: 4.22, F: 5.67 mg/kg/day LOAEL = M: 32.81, F: 43.04 mg/kg/day based on increased mortality in females, decreased body weights and body weight gains in both sexes, and increased esophageal lesions in both sexes No evidence of carcinogenicity
870.4300	Carcinogenicity--mice	NOAEL = M: 41.0, F: 64.6 mg/kg/day LOAEL = M: 149.8, F: 248.1 mg/kg/day based on uterine nodules, hyperplasia in the adrenal gland of males, hyperkeratosis in the esophagus, forestomach, and tongue of females, and acanthosis in the pinnae and tails of females No evidence of carcinogenicity
870.5100	Gene mutation (Ames Test)	Negative, ±S9 up to cytotoxic 1,000 μg/plate

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

Guideline No.	Study Type	Results
870.5395	Cytogenetics	Negative, at clinically toxic i.p. dose
870.5300	Mammalian cells in culture	Negative, ±S9 up to cytotoxic/precipitation 200 μg/mL
870.5375	Chromosome aberrations	Negative, ±S9 up to cytotoxic doses
870.5550	Unscheduled DNA synthesis	Negative, ±S9 up to severe cytotoxicity
870.6200	Acute neurotoxicity screening battery	NOAEL = 10 mg/kg LOAEL = 30 mg/kg based on clinical signs (piloerection and slight to moderate gait incoordination) and FOB effects (decreased forelimb grip strength and foot splay) in males
870.6200	Subchronic neurotoxicity screening battery	NOAEL = M: 2.4, F: 2.5 mg/kg/day LOAEL = M: 10.6, F: 11.1 mg/kg/day based on decreased bodyweight gain, food consumption (males), and hyperkeratosis in the stomach, esophagus, and tongue
870.7485	Metabolism and pharmacokinetics (rats)	Absorption was at least 60–70% and began immediately after administration with peak plasma concentrations at 1.5–2 hours post-dose at 1 mg/kg, and delayed to 8 hours at 100 mg/kg. More than 97% of the recovered radioactivity was excreted via urine and feces within 48 hours in all dose groups and more than 80% within 24 hours. Renal excretion accounted for the majority of the radioactivity (1.8:1 urine:feces on average).
870.7600	Dermal penetration (rats)	Dermal absorption factor: 52.5% at 8 hours

B. Toxicological Endpoints

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

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million(1×10^{-6}), or one in ten million(1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which

carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/Special FQPA SF = 0.1 mg/kg/day.	Acute neurotoxicity in rats LOAEL = 30 mg/kg/day based on clinical signs (piloerection and slight to moderate gait incoordination) and FOB effects (decreased forelimb grip strength and foot splay) in males on day 0-1
Chronic dietary (all populations)	NOAEL = 2.5 mg/kg/day UF = 300 Chronic RfD = 0.0083 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.0083 mg/kg/day	Chronic oral toxicity study in dogs LOAEL = 28.03/25.84 mg/kg/day M/F based on hepatocytomegaly, cataracts, and decreased albumin in males and females; liver discoloration and decreased triglycerides in females; and increased alanine aminotransferase in males
Dermal exposure: Short- and intermediate-term (Residential)	Dermal (or oral) study NOAEL= 5 mg/kg/day	Residential LOC for MOE = N/A	Prenatal toxicity study in rats (Dermal) the maternal LOAEL (systemic) = 20 mg/kg/day based on decreased body weight gains
Dermal exposure: Long-term (Residential)	Oral study NOAEL = 2.5 mg/kg/day (dermal absorption rate = 53%)	Residential LOC for MOE = N/A	Chronic oral toxicity in dogs LOAEL = 28.03/25.84 mg/kg/day (M/F) based on hepatocytomegaly, cataracts, and decreased albumin in males and females; liver discoloration and decreased triglycerides in females; and increased alanine aminotransferase in males
Short-term inhalation (1 to 30 days) (Residential)	Inhalation study NOAEL = 0.087 mg/L = 23.6 mg/kg/day	Residential LOC for MOE = N/A	28–Day inhalation toxicity study in rats LOAEL = 0.518 mg/L = 140.5 mg/kg/day based on decreased body weights and body weight gains, increased incidences of clinical signs of toxicity and dermal irritation, thymic atrophy, and toxicity to the skin, respiratory system, and liver
Intermediate-term inhalation (1–6 months) (Residential)	Inhalation NOAEL = 0.087 mg/L = 23.6 mg/kg/day	Residential LOC for MOE = N/A	Subchronic inhalation toxicity study in rats LOAEL = 0.518 mg/L = 140.5 mg/kg/day based on decreased body weights and body weight gains, increased incidences of clinical signs of toxicity and dermal irritation, thymic atrophy, and toxicity to the skin, respiratory system, and liver

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (greater than 6 months) (Residential)	Oral study NOAEL = 2.5 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = N/A	Chronic oral toxicity study in dogs LOAEL = 28.03/25.84 mg/kg/day M/F based on hepatocytomegaly, cataracts, and decreased albumin in males and females; liver discoloration and decreased triglycerides in females; and increased alanine aminotransferase in males

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Spiroxamine is a new chemical and therefore, these are the first tolerances to be established for the residues of spiroxamine. Tolerance level residues, average residues from field trial data, the concentration/reduction factors from processing studies, and 100% crop treated information were used. Partially refined acute and chronic dietary risk assessments for spiroxamine were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 1.33), which uses food consumption data from the U.S. Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994–1996 and 1998. Risk assessments were conducted by EPA to assess dietary exposures from spiroxamine in food as follows:

i. *Acute exposure.* The acute assessment was a partially refined deterministic assessment. Tolerances were used for the nonblended and partially blended raw agricultural commodities (3.0 ppm for bananas and 1.0 ppm for grapes). For the processed commodities of grapes, the highest average field trial (HAFT) value of 0.613 ppm was used as the residue value, which was computer-multiplied by the processing factors (adjustment factors #1) of 0.67x for grape juice and 1.3x for raisins. For the blended commodity hops, the average residue value from the field trials for imported hops (16 ppm) was used. Data on projected market share or percent crop treated were not used.

ii. *Chronic exposure.* The chronic assessment was a partially refined deterministic assessment. Average residue values from the field trials were used for bananas, grapes, and hops (1.13 ppm for unbagged bananas, 0.17 ppm for grapes, and 16 ppm for imported hops.) The tolerance level for grapes (1.0 ppm) was used for grape leaves and wine. For the processed commodities of grapes other than wine, the average value of 0.17 ppm was used as the residue value, which was computer-multiplied by the processing factors (adjustment factors #1) of 0.67x for grape juice and 1.3x for raisins. Data on projected market share or percent crop treated were not used.

iii. *Cancer.* Spiroxamine has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative risk assessment was not conducted to assess cancer risk.

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

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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.

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

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of spiroxamine for acute and chronic exposures are estimated to be 17.8 parts per billion (ppb), and 14 ppb, respectively for surface water. The EEC of spiroxamine for acute and chronic exposures is 0.27 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).

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

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spiroxamine and any other substances and spiroxamine 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 spiroxamine 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 (OPP) concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There was no evidence for quantitative or qualitative susceptibility following oral or dermal exposures to rats *in utero* or oral exposure to rabbits *in utero*.

There is no concern for neurotoxicity resulting from exposure to spiroxamine.

3. *Conclusion*. The toxicology and exposure data bases for spiroxamine are complete with the exception of certain confirmatory or clarifying studies. The toxicity data base contains acceptable/guideline acute and subchronic neurotoxicity studies; two acceptable/guideline developmental toxicity studies in rats (oral and dermal), and rabbits (oral); and an acceptable/nonguideline 2-generation rat reproduction study. The 2-generation rat reproduction study is classified as acceptable/nonguideline because of questions concerning the increased lactation indices and clinical signs of toxicity in the second generation. There are enough data to satisfy the requirements for a 1-generation reproduction study and the study is acceptable and potentially upgradable to an Acceptable/Guideline study (2-generation reproduction) upon submission of clarifying data regarding the lactation indices and clinical signs of toxicity in the second generation.

In the acute neurotoxicity study in the rat, there was evidence of mild spiroxamine-induced neurotoxicity characterized by piloerection and slight to moderate gait in coordination, and FOB effects of decreased forelimb grip strength and foot splay in males at a dose level of 30 mg/kg/day. In subchronic neurotoxicity studies in the rat, clinical signs, FOB, motor activity, brain weight, ophthalmology, gross necropsy, and neuropathology were unaffected by treatment. Treatment-related effects at 155 ppm (10.6 mg/kg/day) were limited to hyperkeratosis of the esophagus in one male and one female. No treatment-related effects were observed at 35 ppm (2.4 mg/kg/day).

In rat prenatal toxicity studies - oral, developmental toxicity showed no effects of treatment on maternal survival or clinical signs. There were no abortions, premature deliveries, or complete litter resorptions. Similarly, there were no effects of treatment on the number of resorptions (early or late), number of fetuses (live or dead), post-implantation loss, or fetal sex ratio. There were no treatment-related external, visceral, or skeletal variations.

Rat prenatal toxicity studies - dermal, showed there were no effects of treatment on maternal survival, clinical signs, food consumption, or gross pathologly.

In rabbit prenatal toxicity study, there were no effects of treatment on maternal gross pathology or the number of resorptions (early, late, or complete litter), number of fetuses (live or dead), number of litters, post-implantation loss, fetal weights, or sex ratio. There were no treatment-related external or skeletal variations.

4. *Degree of concern analysis and residual uncertainties*. There are no concerns for residual uncertainty for prenatal toxicity in the available developmental studies. However, until clarifying data are provided on the 2-generation rat reproduction study, there is some uncertainty with regard to postnatal toxicity.

A 3X (as opposed to 10X) FQPA data base uncertainty factor was determined to be sufficient to address questions regarding the 2-generation rat reproduction study because the available data from the 1-generation show offspring effects occurring at doses higher than the dose that caused parental effects and the dose (2.5 mg/kg/day) used for driving the chronic RfD is approximately 3-fold lower than the offspring NOAEL (10.8 mg/kg/day). The 3X data base UF should be applied only to the chronic dietary risk assessment because the required study (2-generation reproduction toxicity study) could provide an endpoint applicable to chronic exposure scenario, but not for an acute exposure scenario. There are no residential uses at the present time.

Based on the above data, no special FQPA safety factor (i.e., 1X) is required since there are no residual uncertainties for prenatal toxicity and the lack of a fully acceptable 2-generation toxicity study is addressed by the data base uncertainty factor of 3X.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This

allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to spiroxamine will occupy 7.4% of the aPAD for the U.S. population, 6.2% of the aPAD for females 13 years and older, 27% of the aPAD for infants less than 1 year old, and 31% of the aPAD for children 1–2 years old. In addition, there is potential for acute dietary exposure to spiroxamine in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

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

Population Subgroup	aPAD (mg/kg)	%aPAD/(Food)	Surface Water EEC/(ppb)	Ground Water EEC/(ppb)	Acute DWLOC/(ppb)
U.S. population	0.1	7.4	18	0.27	3,200
Females (13–50 years old)	0.1	6.2	18	0.27	2,800
Infants (less than 1 year old)	0.1	27	18	0.27	730
Children (1–2 years old)	0.1	31	18	0.27	690

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spiroxamine from food will utilize 8.3% of the cPAD for the U.S. population, 6.0% of the aPAD for females 13 years and older, 18% of the cPAD for infants less than 1 year old, and 29% of the cPAD for children 1–2 years old. There are no residential uses for spiroxamine that result in chronic residential exposure to spiroxamine. In addition, there is potential for chronic dietary exposure to spiroxamine in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.– AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SPIROXAMINE

Population/Subgroup	cPAD/mg/kg/day	%/cPAD/(Food)	Surface Water EEC/(ppb)	Ground/Water EEC/(ppb)	Chronic/DWLOC(ppb)
U.S. population	0.0083	8.3	14	0.27	270
Females (13–50 years old)	0.0083	6.0	14	0.27	230
Infants (less than 1 year old)	0.0083	18	14	0.27	70
Children (1–2 years old)	0.0083	29	14	0.27	60

3. *Aggregate cancer risk for U.S. population*. Spiroxamine has been classified as not likely to be carcinogenic to humans. Therefore, spiroxamine is not expected to pose a cancer risk.

4. *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 spiroxamine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A proposed enforcement method (Bayer AG Method No. 00407) for analysis of spiroxamine and its metabolites containing the aminodiol moiety in plants has been submitted. The method was written for grapes and processed commodities. An independent laboratory validation (ILV) was conducted on grapes. Minor modifications were made for analysis of bananas and hops. The method will be adequate for establishment of tolerances and conditional registrations when the confirmatory method is modified to use more than single-ion monitoring or an interference study is conducted, and when the analytical reference standard for N-ethyl-N-propyl-1,2-dihydroxy-3-

aminopropane is sent to the National Pesticide Standards Repository. As a condition of registration (for continued registration) and for continuation of importation of bananas and hops, a method validation for Bayer AG Method No. 00407 must be conducted by EPA's laboratory, however, EPA has conducted a paper review of this method and found the method acceptable.

Using the common moiety method (Bayer AG Method No. 00407), spiroxamine residues are converted to a single analyte, N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane (also known as aminodiol), which is derivatized to and measured as the di-trimethylsilyl derivative. All spiroxamine residues containing the aminodiol moiety are quantitated by gas chromatography/mass selective detector (GC/MSD) operated in a single-ion mode. The data collection method used for the quantitation of residues in grape commodities from the field trial, processing, and storage stability studies is identical to the proposed enforcement method. Minor modifications were made for analysis of bananas and hops.

Adequate enforcement methodology (gas chromotography/mass selective detection), Bayer AG Method No. 00407, is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address:*residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican maximum residue levels or tolerances for spiroxamine. A proposal for registration of spiroxamine on hops in the European Community (Germany) with a maximum residue level of 50.0 ppm is consistent with the proposal for U.S. registration of spiroxamine on hops with a tolerance of 50.0 ppm. The U.S. tolerance of 50.0 ppm was proposed to harmonize with the European Community's proposed maximum residue level. International harmonization is not an issue at this time.

C. Conditions

Additional data are needed in the following areas:

- Banana--Storage stability data are needed on bananas stored frozen for 6 months. Information regarding soil types and temperature recordings for the banana field trials should be submitted if available.
- Hops, dried cones--Additional storage stability information is needed to support the hop field trials which were conducted in Germany.
- Clarifying data on the 2-generation reproduction study for rat pertaining to the increased lactation indices and clinical toxicity in the second generation.

V. Conclusion

Therefore, import tolerances are established for combined residues of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine and its metabolites containing the N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane moiety, in or on grape at 1.0 ppm, banana at 3.0 ppm, and hop, dried cones at 50 ppm (import and U.S. grown).

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0120 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 September 14, 2004.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its

inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0120, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to:*opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 1, 2004.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.602 is added to subpart C to read as follows:

§ 180.602 Spiroxamine; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of

the fungicide spiroxamine (8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine) and its metabolites containing the N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane moiety, calculated as parent equivalent, in or on the following raw agricultural commodities:

Commodity	Parts per million
Banana (import)	3.0
Grape (import)	1.0
Hop, dried cones	50

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

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

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

[FR Doc. 04–16216 Filed 7–15–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL–7787–6]

RIN 2060–AJ07

Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance With the Disposal Regulations; Alternative Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (''EPA'' or ''the Agency'' or ''we'') is finalizing changes to the ''Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations,'' (''Compliance Criteria'') proposed August 9, 2002 (67 FR 51930–51946). Today, after considering public comments received in response to the proposed changes, we finalize the following actions: Addition of a mechanism to address minor changes to the provisions of the Compliance Criteria; changes to the approval process for waste characterization programs at Department of Energy (DOE) transuranic (TRU) waste sites; changes to the number of copies of compliance applications and reference materials submitted to EPA; and replacement of the term ''process knowledge'' with ''acceptable knowledge.'' Today's action will maintain or improve our oversight at WIPP to ensure safe disposal of waste. Moreover, these changes do not modify the technical approach that EPA employs when conducting independent inspections of the waste characterization capabilities at DOE waste generator/storage sites. EPA is conducting this action in accordance with the procedures for substituting alternative provisions in the Compliance Criteria.

DATES: This final rule is effective October 14, 2004.

FOR FURTHER INFORMATION CONTACT: Ray Lee; telephone number: (202) 343–9463; postal address: Radiation Protection Division, Mail Code 6608J, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OAR–2002–0005. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at: Air and Radiation Docket and Information Center, Room B–108, U.S. Environmental Protection Agency, 301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m.–4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–1742.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''Federal Register'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. Once in the system, select ''search,'' then key in the appropriate docket identification number (OAR–2002–0005 for this action).

Abbreviations Used in This Document

AK—Acceptable Knowledge
ANL–E—Argonne National Laboratory-East
APA—Administrative Procedure Act
BID—Background Information Document
CBFO—Carlsbad Field Office
CFR—Code of Federal Regulations
CH—Contact Handled
DOE—Department of Energy
EPA—Environmental Protection Agency
INEEL—Idaho National Energy and Engineering Laboratory
LANL—Los Alamos National Laboratory
NDA—Nondestructive Assay
NPRM—Notice of Proposed Rulemaking
NRC—Nuclear Regulatory Commission
NTS—Nevada Test Site
ORNL—Oak Ridge National Laboratory
PK—Process knowledge
RFETS—Rocky Flats Environmental Technology Site
RTR—Real-time radiography
SRS—Savannah River Site
TRU—Transuranic
VE—Visual inspection
WC—Waste characterization
WIPP—Waste Isolation Pilot Plant
WIPP LWA—WIPP Land Withdrawal Act
WWIS—WIPP Waste Information System

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