PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

Subpart G—Control Strategy

■ 2. Section 51.121 is amended by adding paragraph (s) to read as follows:

§ 51.121 Findings and requirements for submission of State implementation plan revisions relating to emissions of oxides of nitrogen.

* * * * *

(s) Stay of Finding of Significant Contribution with respect to the 1-hour standard. Notwithstanding any other provisions of this subpart, the effectiveness of paragraph (a)(1) of this section is stayed as it relates to the State of Georgia, only as of September 30, 2005.

[FR Doc. 05–17031 Filed 8–30–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0224; FRL–7732–3]

Methoxyfenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of methoxyfenozide in or on sorghum grain, sorghum grain forage, and sorghum grain stover. 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 sorghum grain. This regulation establishes a maximum permissible level for residues of methoxyfenozide in these food commodities. These tolerances will expire and are revoked on December 31, 2007.

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–2005–0224. 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: Stacey Milan Groce, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–2505; e-mail address: *milan.stacey@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 tolerances for residues of the insecticide methoxyfenozide, benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, in or on sorghum grain at 0.05 parts per million (ppm), sorghum grain forage at 15 ppm, and sorghum grain stover at 125 ppm. These tolerances will expire and are revoked on December 31, 2007. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish time-limited tolerances or exemptions from the requirement of 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 section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the 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 the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes

exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Methoxyfenozide on Sorghum Grain, Sorghum Grain Forage, Sorghum Grain Stover and FFDCA Tolerances

The southwestern corn borer is a major pest on corn, but has become problematic for Louisiana sorghum producers in recent years. The southwestern corn borer is known to infest grain sorghum and had not been documented as an important pest of this crop until 2002, when heavy moth infestations developed in corn and migrated to late planted sorghum fields. Grain sorghum is usually planted in the spring, but adverse weather conditions and planting conflicts ensure that a significant amount of acreage will be planted late. These conditions can provide a susceptible host for heavy southwestern corn borer moth flight during late summer. This unexpected heavy migration into grain sorghum has left many growers without adequate technology to control this pest.

The sugarcane borer is a major pest of corn grown in the vicinity of sugarcane. The sugarcane borer recently became an important pest of corn in parts of Louisiana where no sugarcane is produced. This northern shift in the infestation range of the sugarcane borer is likely the result of mild winters and an increase in reduced tillage crop production, which has allowed this pest to become established outside of its normal range. Heavy populations of sugarcane borer moth infestations have migrated to late planted sorghum fields and growers have been ill-prepared in handling this disease.

The Louisiana State AgCenter recommends the following two insecticides: Cypermethrin and lambda-cyhalothrin for control of the southwestern corn borer when they are applied before the larvae bore into the stalk. However, the short-lived residual effectiveness of both pyrethroids requires an effective scouting program to carefully time applications. This practice is not available in Louisiana and there are currently no insecticides registered for control of the sugarcane borer on grain sorghum. Methoxyfenozide is a suitable alternative because of its moderate residual life and low risk to humans and most non-target organisms.

Planting grain sorghum early is an important management practice against both the southwestern corn borer and the sugarcane borer. Early planted sorghum usually matures before southwestern corn borer and sugarcane borer populations reach their peak migration from their host plants. However, this practice is limited by weather conditions, which often delay planting sorghum acreage until late spring and early summer. Shredding the crop stubble followed by tillage is no longer feasible since most sorghum is now grown under reduced tillage conditions. Natural enemies destroy large numbers of the southwestern corn borer, but not at levels necessary to prevent significant loss. EPA has authorized under FIFRA section 18 the use of methoxyfenozide on grain sorghum to control southwestern corn borer and sugarcane borer for use on grain sorghum in Louisiana. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of methoxyfenozide in or on sorghum grain, sorghum grain forage, and sorghum grain stover. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sorghum grain, sorghum grain forage, sorghum grain stover after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether methoxyfenozide meets EPA's registration requirements for use on sorghum grain, sorghum grain forage, sorghum grain stover or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serves as a basis for registration of methoxyfenozide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for methoxyfenozide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of methoxyfenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for residues of methoxyfenozide in or on sorghum grain at 0.05 ppm, sorghum grain forage at 15 ppm, and sorghum grain stover at 125 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. 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 endpoint. 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 intra species differences.

For dietary risk assessments (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where + the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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

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

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METHOXYFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age and the general population including infants and children)	None	None	No appropriate endpoint was identified in the oral toxicity studies, including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits
Chronic dietary all populations	NOAEL = 10.2 mg/kg/day UF = 100 Chronic RfD = 0.10 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.10 mg/kg/day	2–Year combined chronic feeding/carcinogenicity, rats LOAEL = 411 mg/kg/day based on hematological changes (decreased RBC, hemoglobin and hematocrit), liver toxicity (increased weights, hypertrophy), histopathological changes in thyroid (increased follicular cell hyppertrophy, altered colloid), possible adrenal toxicity (increased weights)
Short-term, intermediate-term, long-term dermal and Inhalation	None	None	No systemic toxicity was observed at the limit dose following repeated dermal application to rats Based on low vapor pressure, the low acute toxicity of both the technical and formulated products as well as the application rate and application method, there is minimal concern for inhalation exposure.
Cancer (oral, dermal, inhalation)	Methoxyfenozide has been classified as a ''not likely'' human carcinogen		The classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxocity in an acceptable battery of mutagenicity studies

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.544) for the residues of methoxyfenozide, in or on a variety of raw agricultural commodities including the pome fruits crop group, apple pomace, cotton seed, cotton gin byproducts, sweet corn, field corn, milk, meat, fat, liver, and meat byproducts of cattle, goats, hogs, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from methoxyfenozide in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-

use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits. Therefore, acute dietary risk assessments were not conducted.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of agriculture (USDA) 1989–1992 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% of all crops were treated and all resulting residues were at tolerance level.

iii. *Cancer*. Methoxyfenozide has been classified as a ''not likely human carcinogen.'' The classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies. Therefore, risk assessments to estimate cancer were not conducted.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (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 (PC) area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the PRZM/EXAMS to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a PC area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

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

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of methoxyfenozide for chronic exposures are estimated to be 30 parts per billion (ppb) for surface water and 3.5 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).

Methoxyfenozide 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 methoxyfenozide and any other substances and methoxyfenozide 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 methoxyfenozide 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/*.

C. Safety Factor for Infants and Children

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

2. *Developmental toxicity studies*. In a developmental toxicity study in rats regarding maternal findings, there were no deaths orclinical signs, nor were there any effects on body weights or food consumption. No changes were noted in any of the reproductive parameters. Fetal examinations did not

reveal any effects on body weight or gross/visceral/skeletal aspects. The maternal NOAEL is 1,000 milligram/kilogram/day (mg/kg/day) Highest dose tested (HDT) and the maternal LOAEL is greater than 1,000 mg/kg/day. The developmental NOAEL is 1,000 mg/kg/day and the developmental LOAEL is greater than 1,000 mg/kg/day.

In a developmental toxicity study in rabbits regarding maternal findings, there were no deaths or clinical signs, nor were there any effects on body weights, weight gains, or food consumption. No changes were noted in any of the reproductive parameters. Fetal examinations did not reveal any effects on body weight or gross/visceral/skeletal aspects. The maternal NOAEL is 1,000 mg/kg/day HDT, and the maternal LOAEL is greater than 1,000 mg/kg/day. The developmental NOAEL is 1,000 mg/kg day and the developmental LOAEL is greater than 1,000 mg/kg day.

3. *Reproductive toxicity study*. In a 2-generation reproduction study, the LOAEL for systemic toxicity is 20,000 ppm (1,551.9 mg/kg day), based on increased absolute and relative liver weights in males and females and on the hepatocellular hypertrophy in males and females. The NOAEL for systemic toxicity is 2,000 ppm (153.4 mg/kg/day). There were no treatment related reproductive effects on the P_1 and P_2 males and females or their F_1 and F_2 offspring. Therefore, the NOAEL for reproductive toxicity is greater than 20,000 ppm (1,551.9–2,036.5 mg/kg day) HDT. The LOAEL for reproductive toxicity was not identified.

4. *Neurotoxicity.* In an acute oral neurotoxicity study in rats, there were no observable signs of a neurotoxic effect at the highest concentration in females. Functional observational battery (FOB) assessment on day 0 revealed a decrease in hindlimb grip strength for males in the 2,000 mg/kg group. Motor activity assessment remained comparable to controls throughout the study for males and females in all exposure groups. No neuropathological endpoints were observed during the histological examinations of the peripheral or central nervous systems of these animals at any exposure concentration. Based on the absence of any substance related effects on body weight or body weight gain and any clinical signs of toxicity, the NOAEL for systemic toxicity is a concentration of 2,000 mg/kg for males and females. The NOAEL for neurotoxic effects is 200 mg/kg for females. Based on a decrease in hindlimb grip strength on day 0 in the 2,000 mg/kg male group, the NOAEL for males is 1,000 mg/kg and the LOAEL for males is 2,000 mg/kg. No LOAEL was established for systemic effects in males or females or for neurotoxic effects in females.

In a subchronic oral neurotoxicity study in rats, there were no observable signs of a neurotoxic effect at the highest concentration in males or females. FOB and MA remained comparable to controls throughout the study and no neuropathological endpoints were observed during the histological exams of these animals at any exposure concentration. Based on the absence of any substance related effects on body weight or body weight gain and any clinical signs of toxicity, the NOAEL for systemic toxicity is also 2,000 ppm for males (1,318 mg/kg/day), and females (1,577 mg/kg/day). No LOAEL was established for systemic or neurotoxic effects.

In none of the other oral toxicity studies on methoxyfenozide were there any signs of neurotoxicity. The studies considered included all the available toxicology studies on methoxyfenozide.

5. *Conclusion*. There is a complete toxicity data base for methoxyfenozide and no additional studies are required at this time. The scientific and regulatory quality of the toxicology data base for methoxyfenozide is high and is considered sufficient to clearly define the toxicity of this chemical. There is, therefore, high confidence in the hazard and dose-response assessments conducted for this chemical. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

The toxicology data provided no indication of increased susceptibility in rats or rabbits from *in utero* and/or post natal exposure to methoxyfenozide. In the prenatal developmental toxicity studies in rats and rabbits, no developmental toxicity was observed at the limit dose, which is the HDT. In the 2-generation reproduction study in rats, no effects in the offspring were observed at the HDT. In none of the oral toxicity studies on methoxyfenozide were there any signs of neurotoxicity. The studies considered included all the available toxicology studies on methoxyfenozide.

Therefore, the Agency has determined that the FQPA Safety Factor (as required by the FQPA of August 3, 1996) can be reduced to 1X in assessing the risk posed by this chemical.

D. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA 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 methoxyfenozide 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 methoxyfenozide on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits. Therefore, acute dietary risk assessments were not conducted.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to methoxyfenozide from food will utilize 23% of the cPAD for the U.S. population, 37% of the cPAD

for all infants < 1–year old, the infant subpopulation at greatest exposure and 71% of the cPAD for children 1-2 years old, the children subpopulation at greatest exposure. There are no residential uses for methoxyfenozide that result in chronic residential exposure to methoxyfenozide. In addition, despite the potential for chronic dietary exposure to methoxyfenozide in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of methoxyfenozide in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO METHOXYFENOZIDE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.10	23	30	3.5	2,700
Infants (< 1–year old)	0.10	37	30	3.5	630
Children (1-2 years old)	0.10	71	30	3.5	290

3. *Short-term risk*. Short-term and intermediate-term aggregate exposures take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide 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 were previously addressed.

4. *Aggregate cancer risk for U.S. population*. Methoxyfenozide has been classified as a ''not likely'' human carcinogen. The classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies. Therefore, risk assessments to estimate cancer risk were not conducted.

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 methoxyfenozide residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method for use on corn matrices (grain, forage, stover) is TR 34–00–38. Information on the analytical methodology may be requested from: Calvin Furlow, Public Information Resources and Services Branch (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C, 20460, telephone number: (703) 305–5229; e-mail address: *furlow.calvin@epa.gov*.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican limits for residues of methoxyfenozide in or on plant or animal commodities. Therefore, no compatibility issues exist regarding the proposed U.S. tolerances.

C. Conditions

Plantback (recropping) restrictions should appear on the registered labels. These restrictions should specify that the crops for which methoxyfenozide use is registered may be replanted at any time, and all other crops grown for food or feed may be replanted after 7 days.

The existing livestock tolerances are adequate for the uses proposed under these emergency exemptions.

VI. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide, benzoic acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, in or on grain sorghum at 0.05 ppm, grain sorghum forage at 15 ppm, and grain sorghum stover at 125 ppm.

VII. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0224 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 2005. 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 VII.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 the docket ID number OPP–2005–0224, 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).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances] under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. 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 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]

BILLING CODE 6560–50–S

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,