(1) *Parameter monitoring.* For determining the ethylene oxide concentration required in § 63.364(e), follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS–8.

(2) *Initial compliance.* For determining the ethylene oxide concentration required in § 63.363(c)(2), the procedures outlined in Method 18 or Method 25 A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A test consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate and report Method 25A instrument results using ethylene oxide as the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device.

(d) *Efficiency determination at the aeration room vent (not manifolded).* The following procedures shall be used to determine the efficiency of a control device used to comply with § 63.362(d), the aeration room vent standard.

(1) Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Method 18 or 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

(2) Determine control device efficiency (% Eff) using the following equation:

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

Where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_O = mass flow rate out of the control device

(3) Repeat the procedures in paragraphs (d)(1) and (2) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

* * * * *

(f) [Reserved]

* * * * *

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the requirements of § 63.363 or § 63.364, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Administrator may request further information and will specify appropriate test methods and procedures.

8. Section 63.366 is amended by revising paragraph (a)(3) to read as follows:

§ 63.366 Reporting requirements.

(a) * * *

(3) Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per § 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see § 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in Table 1 of § 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

* * * * *

9. Section 63.367 is revised to read as follows:

§ 63.367 Recordkeeping requirements.

(a) The owner or operator of a source subject to § 63.362 shall comply with the recordkeeping requirements in § 63.10(b) and (c), according to the applicability in Table 1 of § 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to § 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(d) The owners or operators complying with § 63.363(b) (4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

[FR Doc. 01–27594 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301185; FRL–6806–4]

RIN 2070–AB78

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 field corn grain, stover and oil, aspirated grain fractions and soybean forage, hay, oil, and seed. 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 field corn and soybeans. This regulation establishes a maximum permissible level for residues of methoxyfenozide in these food commodities. The tolerances will expire and are revoked on December 31, 2003.

DATES: This regulation is effective November 2, 2001. Objections and requests for hearings, identified by docket control number OPP–301185, must be received by EPA on or before January 2, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301185 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide

Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463; and e-mail address: Madden.Barbara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/*. To access this document, on the homepage select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html*, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301185. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

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 field corn grain at 0.02 part per million (ppm), field corn forage at 10 ppm, field corn stover at 75 ppm, corn oil at 0.1 ppm, aspirated grain fractions at 20 ppm, soybean seed at 0.04 ppm, soybean forage at 10 ppm, soybean hay at 75 ppm and soybean oil at 1.0 ppm. These tolerances will expire and are revoked on December 31, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 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) 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) 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 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 August 3, 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Methoxyfenozide on Field Corn and Soybeans and FFDCA Tolerances

Field Corn - The southwestern corn borer (Pyralidae: *Diarrhea grandiosella*) is one of several major corn pests in the southern United States. There are usually three generations per year. First generation larvae feed in the whorl, where it is susceptible to foliar insecticide applications. Second and third generation larvae bore into the stalk, where they are protected from insecticide applications. Larvae tunnel down the main stem to the base of the plant and overwinter in the crown of the corn stalk, just below soil surface, where they are susceptible to death by freezing, drowning, or mechanical destruction.

The Mississippi University Cooperative Extension Service recommends the following chemicals for southwestern corn borer control: Carbaryl, carbofuran, chlorpyrifos, cyhalothrin, esfenvalerate, and permethrin. According to the Mississippi application frequent summer rains have affected the effectiveness of the registered pesticides, most of which have short residual lives, resulting in poor southwestern corn borer control and

increasing the need for repeated applications. Furthermore, corn farmers in Mississippi, mostly small farmers who also grow catfish in ponds and handle and apply pesticides themselves, avoid using carbofuran, which is perceived as hazardous to themselves and their catfish. Methoxyfenozide, an IGR specific to lepidopteran larvae, was identified as a suitable alternative because of its moderate residual life and low risk to humans and most non-target organisms.

Transgenic Bt corn is an effective alternative, but is limited to 50% of the acreage planted due to resistance management compliance. Natural enemies destroy a portion of the southwestern corn borer population, but not at levels necessary to prevent economic losses. In the past, destruction of corn stubble by shredding, disking, or deep tillage was an effective cultural control method. However, under the present no-till conservation practices, larger numbers of overwintering larvae survive and infest the next year's crop.

The request indicates that yield reductions associated with southwestern core borer infestations have been reported in the range of 10% to 50%.

Soybean - Saltmarsh caterpillars (often called ''woolly worms'') feed in the larval stage in groups on soybean foliage. It feeds on the leaves on the upper third of the soybean canopy. The saltmarsh caterpillar has historically been only an occasional pest of soybeans in Arkansas and Mississippi. Although it is usually present in soybean fields, it is rarely at population densities to cause economic damage. However, due to favorable conditions, population densities of the saltmarsh caterpillar have been increasing over the last few years.

While environmental conditions played a role in the recent saltmarsh caterpillar outbreaks, the inability to control the pest with currently registered insecticides was the primary cause for yield loss. Control of the pest with currently registered insecticides (thiodicarb, esfenvalerate, and spinosad) was seldom greater than 50%. This required multiple, short interval, high rate insecticide applications with associated increase in cost. Soybeans which suffered the greatest impact were the late maturing varieties.

EPA has authorized under FIFRA section 18 the use of methoxyfenozide on field corn for control of Southwestern corn borer in Mississippi and for use on soybeans to control Saltmarsh caterpillars in Arkansas and Mississippi. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of methoxyfenozide in or on field corn and soybeans. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) 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). Although these tolerances will expire and are revoked on December 31, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on field corn and soybeans 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 field corn and soybeans or whether a permanent tolerance for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve 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 Arkansas and Mississippi to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions 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 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).

Consistent with section 408(b)(2)(D), 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), for time-limited tolerances for residues of methoxyfenozide in or on field corn grain at 0.02 ppm, field corn forage at 10 ppm, field corn stover at 75 ppm, corn oil at 0.1 ppm, aspirated grain fractions at 20 ppm, soybean seed at 0.04 ppm, soybean forage at 10 ppm, soybean hay at 75 ppm and soybean oil at 1.0 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 intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety 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 Safety Factor.

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 hypertrophy, altered colloid), possible adrenal toxicity (increased weights).
Short-term, intermediate-term, and long-term dermal and inhalation	None	None	No systemic toxicity was seen 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 genotoxicity in an acceptable battery of mutagenicity studies.

* The reference to the FQPA Safety Factor refers to any additional safety factor 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, milk, and 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 one

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

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

C. Safety Factor for Infants and Children

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

2. *Developmental toxicity studies*. In a developmental toxicity study in rats regarding maternal findings, there were no deaths or clinical signs, nor where 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 affects on body weight or gross/visceral/skeletal aspects. The maternal NOAEL is 1,000 mg/kg/day (Highest Dose Tested (HDT), Limit Dose (LD)) 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 where 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 affects on body weight or gross/visceral/skeletal aspects. The maternal NOAEL is 1,000 mg/kg/day (HDT, LD) and the maternal LOAEL is greater than 1,000 mg/kg/day. The developmental NOAEL is greater than 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 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 P1 and P2 males and females or their F1 and F2 offspring. Therefore, the NOAEL for reproductive toxicity is greater 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 even 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 (MA) 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 2,000 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 even 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 examinations 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 20,000 ppm for males (1,318 mg/kg/day) and females (1,577 mg/kg/day). The NOAEL for neurotoxic effects is also 20,000 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*. The toxicology data base for methoxyfenozide is complete 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 postnatal exposure to methoxyfenozide. In the prenatal developmental toxicity studies in rats and rabbits, no developmental toxicity was observed at the LD, 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 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 the USEPA Office of Water are used to calculate DWLOCs: 2L/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 3% of the cPAD for the U.S. population, 13% of the cPAD for all infants (< 1year), the infant subpopulation at greatest exposure and 9% of the cPAD for children (1–6 years old), the children subpopulation at greatest exposure. There are no residential uses registered for 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 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	3	30	3.5	3,400
Children (1–6 years old)	0.10	9	30	3.5	900
Infants (< 1 year old)	0.10	13	30	3.5	870

3. *Short-term risk and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes 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 may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 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 with regard to the proposed U.S. tolerances.

C. Conditions

A 1–year plant back interval is required for crops not having tolerances. Currently, there is a petition under review that may result in rotational crop tolerances being established allowing for shorter plant back intervals. But, in the absence of such tolerances, a 1–year plant back interval is required.

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 field corn grain at 0.02 ppm, field corn forage at 10 ppm, field corn stover at 75 ppm, corn oil at 0.1 ppm, aspirated grain fractions at 20 ppm, soybean seed at 0.04 ppm, soybean forage at 10 ppm, soybean hay at 75 ppm and soybean oil at 1.0 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301185 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 January 2, 2002.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

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.

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.

3. *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 Unit I.B.2. Mail your copies, identified by the docket control number OPP–301185, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. 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 FFDCA section 408, 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General

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: October 18, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. Section 180.544 is amended by adding text to paragraph (b) to read as follows.

§ 180.544 Methoxyfenozide; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insecticide methoxyfenozide in connection with the use of the pesticide under section 18 emergency exemption granted by EPA. The tolerances will expire on the dates specified in the following tables.

Commodity	Parts per million	Expiration/revocation date
Corn, field, forage	10	12/31/03
Corn, field, grain	0.02	12/31/03
Corn, field, stover	75	12/31/03
Corn, oil	0.1	12/31/03
Soybean, aspirated grain fractions	20	12/31/03
Soybean, forage	10	12/31/03
Soybean, hay	75	12/31/03
Soybean, refined oil	1.0	12/31/03
Soybean, seed	0.04	12/31/03

* * * * *

[FR Doc. 01–27603 Filed 11–1–01; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Parts 101–3 and 102–84

[FPMR Interim Rule A–1]

RIN 3090–AG55

Annual Real Property Inventories

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Interim rule.

SUMMARY: The General Services Administration (GSA) is revising the Federal Property Management Regulations (FPMR) by moving coverage on the annual real property inventories into the Federal Management Regulation (FMR). A cross-reference is added to the FPMR to direct readers to the coverage in the FMR. The FMR coverage is written in plain language to provide agencies with updated regulatory material that is easy to read and understand.

DATES: *Effective Date*: November 2, 2001.

Comment Date: Your comments must reach us by January 2, 2002 to be considered in the formulation of a final rule.

ADDRESSES: Send written comments to Mr. Michael E. Hopkins, Regulatory Secretariat (MVP), Acquisition Policy Division, General Services Administration, 1800 F Street, NW., Washington, DC 20405.

Send e-mail comments to *RIN.3090-AG55@gsa.gov*.

FOR FURTHER INFORMATION CONTACT: Stanley C. Langfeld, Director, Real Property Policy Division, (202) 501–1737.

SUPPLEMENTARY INFORMATION:

A. Background

In furtherance of its leadership role in real property asset management, the Office of Governmentwide Policy, Office of Real Property, conducted a comprehensive review of the policies contained in Federal Property Management Regulations (FPMR) Part 101–3, entitled ''Annual Real Property Inventories.'' This review was based on a collaborative effort with Federal real property holding agencies that utilize the Worldwide Inventory of Federal Real Property.

Representatives from the Department of the Interior, the Department of Energy, and the Army Corps of Engineers participated with GSA in conducting the initial steps of the comprehensive review of the policies in FPMR part 101–3. The review focused on improvements to make the real property inventory program more useful and to enable Federal agencies to more effectively manage their real property inventories. In addition, we have rewritten these regulations in plain language format. These regulations are being transferred from the FPMR to the FMR to enable the Government to better focus on implementing statutory requirements, Executive Orders, and governmentwide policies rather than on detailed operating procedures.

B. Executive Order 12866

GSA has determined that this interim rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

C. Regulatory Flexibility Act

This interim rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act does not apply.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this interim rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This interim rule is also exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.