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.

VIII. 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: June 11, 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 180.570 is added to read as follows:

§ 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) *General.* Tolerances to expire on June 21, 2004 are established for residues of isoxadifen-ethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate, CAS No. 163520–33–0) and its metabolites: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β-hydroxy-β-benezenepropanenitrile when in the commodities listed below. This safener will be used only in conjunction with the active ingredient fenoxaprop-p-ethyl, at a rate of 0.17 pound of safener per pound of active ingredient.

Commodity	Parts per million	Expiration/Revocation Date
Rice, bran	0.80 ppm	June 21, 2004
Rice, grain	0.10 ppm	June 21, 2004
Rice, hulls	0.50 ppm	June 21, 2004
Rice, straw	0.25 ppm	June 21, 2004

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

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

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

[FR Doc. 01–15613 Filed 6–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301138; FRL–6787–7]

RIN 2070–AB78

Mesotrione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues ofmesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on field corn. Syngenta Crop Protection Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301138, must be received by EPA on or before August 20, 2001.

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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control numberOPP–301138 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller,Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703-305-6224; and e-mail address: Miller.Joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 t 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 Home Page at http://www.epa.gov/. To access this document, on the Home Page 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. 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–301138. 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, Crystal 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

In the **Federal Register** of May 29, 1998 (63 FR 29401) (FRL–5791–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F4954) for tolerance by Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing. The petition was subsequently transferred to Syngenta Crop Protection Inc., 410 Swing Road, PO Box 18300, Greensboro, NC 27419–8300

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on the raw agricultural commodities field corn, field corn fodder and field corn forage at 0.01 part per million (ppm). EPA is editorially correcting the tolerances expression to read: field corn grain, field corn forage and field corn stover at 0.01 ppm.

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....''

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on field corn grain, field corn forage and field corn stover at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = 0.41/0.47 milligram (mg)/kilogram (kg)/day (males [M]/females [F]) LOAEL = 0.63/0.71 mg/kg/day (M/F), based upon corneal lesion in males

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

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = 0.09/0.10 mg/kg/day (M/F) LOAEL = 11/13 mg/kg/day (M/F), based upon corneal abnormalities in both sexes and decreased body weight gain in males
870.3100	90–Day oral toxicity rodents (mouse)	NOAEL = 1212/1537 mg/kg/day (M/F) LOAEL greater than (>) 1212/1537 mg/kg/day (M/F). No effects noted
870.3150	90–Day oral toxicity in nonrodents (dog)	NOAEL = 1,000 mg/kg/day (M/F) LOAEL > 1,000 mg/kg/day (M/F) No effects noted
870.3200	21/28–Day dermal toxicity (rabbit)	NOAEL = 1,000 mg/kg/day (M/F) LOAEL > 1,000 mg/kg/day (M/F). No systemic effects noted
870.3700a	Prenatal developmental in rodents (rat)	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day, based upon decreased maternal body weight gains during treatment and decreased food consumption Developmental NOAEL was not established LOAEL = 100 mg/kg/day, based upon delays in skeletal ossification and changes in *manus/pes* ossification assessments
870.3700a	Prenatal developmental in rodents (mouse)	Maternal NOAEL = 600 mg/kg/day LOAEL >600 mg/kg/day; No effects noted Developmental NOAEL = 150 mg/kg/day LOAEL = 600 mg/kg/day, based upon decreased ossification of the cervical vertebrae centra
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL was not established LOAEL = 0.3 mg/kg/day (M/F), based upon significantly increased plasma tyrosine levels and increased liver weights in F2 males Offspring/Systemic NOAEL not established LOAEL = 0.3 mg/kg/day (M/F), based upon significantly increased plasma tyrosine levels in F2 male pups Reproductive NOAEL = 0.3 mg/kg/day LOAEL = 1.1/1.2 mg/kg/day (M/F), based upon decreased F2 mean litter size
870.3800	Reproduction and fertility effects (mouse)	Parental/Systemic NOAEL = 10.1/11.7 mg/kg/day (M/F) LOAEL = 71.4/82.5 mg/kg/day (M/F), based upon increased kidney weights and tyrosinemia in the and F1 males Offspring/Systemic NOAEL not established LOAEL = 2.1/2.4 mg/kg/day (M/F), based upon tyrosinemia and ocular discharge in the F1 and F2 offspring Reproductive NOAEL = 1455.5/1652.3 mg/kg/day (M/F) LOAEL > 1455.5/1652.3 mg/kg/day
870.4100a	Chronic toxicity rodents (mouse)	NOAEL = 56.2/72.4 mg/kg/day (M/F) LOAEL = 1114/1494.5 mg/kg/day (M/F), based upon decreases in body weight gain and food utilization in males
870.4100b	Chronic toxicity dogs	NOAEL was not established LOAEL = 10 mg/kg/day, based upon evidence of tyrosinemia in both sexes and increased incidence of erythrophagocytosis in the mesenteric lymph nodes of females
870.4300	Combined chronic toxicity/carcinogenicity rodents (rat)	NOAEL was not established NOAEL = 0.16/0.19 mg/kg/day (M/F) ocular lesions only] LOAEL = 0.16/0.19 mg/kg/day based kidney and liver weights or hepatocyte fat vacuolation in males LOAEL = 0.48/0.57 mg/kg/day (M/F), based upon ocular lesions, increases in kidney and liver weights, and hepatocyte fat vacuolation in females No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 49.7/63.5 mg/kg/day (M/F)

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

Guideline No.	Study Type	Results
		LOAEL = 898/1103 mg/kg/day (M/F), based upon decreased body weight, body weight gain, and food efficiency in males No evidence of carcinogenicity
870.5100	Gene Mutation reverse gene mutation assay in bacteria	There was no evidence of induced mutant colonies over background
870.5300	Gene Mutation *in vitro* forward gene mutation assay in mouse lymphoma cells	There were no treatment-related increases in mutant frequency in the presence or absence of S9 activation
870.5375	Cytogenetics *in vitro* mammalian cytogenetics assay	Not clastogenic with S9 activation and equivocal for clastogenic activity without S9 activation
870.5395	bone marrow micronucleus assay	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time.
870.6200a	Acute neurotoxicity screening battery	NOAEL = 2,000 mg/kg/day (M/F) LOAEL > 2,000 mg/kg/day (M/F) No effects noted
870.6200b	Subchronic neurotoxicity screening battery	NOAEL = 0.20/0.23 mg/kg/day (M/F) LOAEL = 8.25/9.29 mg/kg/day (M/F), based upon corneal opacities and/or vascularization of the cornea of the eye in males
870.7485	Metabolism rat	Mesotrione was readily absorbed and distributed in the body. Tissue distribution was about the same in both sexes, although one study showed higher residues in the kidneys in females, with the highest residues of the test compound in the liver and kidney. Higher doses resulted in higher residues in the liver and kidney, while repeated doses resulted in reduced accumulation of residues in all tissues. Levels of radioactivity in tissues of iv-dosed animals were essentially the same as in orally-dosed animals. Over 50% of the administered dose was excreted in the urine in both sexes and around 25% was excreted in the feces within 72 hours. Females exhibited slightly higher total urinary excretion than males, but total fecal excretion was about the same in both sexes. Increasing the dose or repeated doses had little effect on the pattern of excretion in both sexes. The overall pattern of excretion was similar between orally-dosed and iv-dosed rats. The metabolite profile was similar between the sexes in each group and between the single-dosed and repeated-dosed animals. The parent compound, mesotrione, was the major component identified in the urine (> 47%) and feces (> 55%). Minor metabolites identified were MNBA, AMBA, 5-hydroxymesotrione, and 4-hydroxymesotrione.
870.7485	Metabolism mouse	Metabolism in the mouse was very similar to the rat (above) except that males had slightly increased total fecal excretion when compared to females and, females in the low-dose group excreted higher (1.5x) levels of parent compound in the urine than males. Free mesotrione was the major component in the urine and feces (≥ 50% of the dose). Minor components in the fecal extracts included AMBA and MNBA.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences. A UF of 3 is used if no NOAEL was achieved in the toxicology study.

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 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 mesotrione used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MESOTRIONE 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 all populations	Not Applicable	Not Applicable	No appropriate study available.
Chronic Dietary all populations	LOAEL= 2.1 mg/kg/day; UF = 300 [10 x 3]; Chronic RfD = 0.007 mg/kg/day	FQPA SF = 10X; cPAD = chronic RfD/FQPA SF = 0.0007 mg/kg/day	Reproduction Study - mouse Offspring LOAEL = 2.1 mg/kg/day based upon tyrosinemia in F1 and F2a offspring and ocular discharge in F1 pups**.
Oral, Short-term (1-7 days) (Residential)	No residential uses. An endpoint was not proposed/selected.		
Oral, Intermediate-term (1 week - several months) (Residential)	No residential uses. An endpoint was not proposed/selected.		
Cancer (oral, dermal, inhalation)	not likely	Not Applicable	Acceptable oral rat and mouse carcinogenicity studies; no evidence of carcinogenic or mutagenic potential.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

** Plasma tyrosine levels were increased in the rat, mouse and dog in the chronic and reproduction studies in which levels were measured. The ocular, liver and kidney effects are believed to be mediated by the high tyrosine levels in the blood caused by inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD). Even though the rat is the most sensitive species to this effect compared to the dog and the mouse, EPA concludes that the mouse is a more appropriate model for assessing human risk than is the rat.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. No tolerances have been previously established (40 CFR part 180) for residues of mesotrione in or on any variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from mesotrione 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 study available show any acute dietary effects of concern.

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: residue levels are at the recommended tolerances for field corn, and 100% of the crop field corn is treated with mesotrione. The %cPAD for the general U.S. population is 1.8% and for the most sensitive population subgroups, All Infants (< 1 year old), is 4.3%.

iii. *Cancer*. Acceptable oral rat and mouse carcinogenicity studies showed no evidence of carcinogenic or mutagenic potential.

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

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 groundwater. 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 mesotrione they are further discussed in the aggregate risk sections below.

Based on the GENEEC (Version 1.2) and SCI-GROW models the estimated environmental concentrations (EECs) of mesotrione for acute exposures are estimated to be 20 parts per billion (ppb) for surface water and 0.15 ppb for ground water. The EECs for chronic exposures are estimated to be 4.3 ppb for surface water and 0.15 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). Mesotrione 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 mesotrione 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, mesotrione 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 mesotrione 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).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. There is quantitative evidence of increased susceptibility demonstrated in the oral prenatal developmental toxicity studies in rats, mice, and rabbits. Delayed ossification was seen in the fetuses at doses below those at which maternal toxic effects were noted. Maternal toxic effects in the rat were decreased body weight gain during treatment and decreased food consumption and in the rabbit, abortions and GI effects.

2. *Conclusion*. The FQPA safety factor (10x) is retained in assessing the risk posed because there is quantitative evidence of increased susceptibility of the young exposed to mesotrione in the prenatal developmental toxicity studies in mice, rats, and rabbits and in the multi-generation reproduction study in mice, there is qualitative evidence of increased susceptibility of the young exposed to mesotrione in the multi-generation reproduction study in rats; and a Developmental Neurotoxicity Study is required to assess the effects of tyrosinemia on the developing nervous system exposed to mesotrione.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates drinking water level of comparison (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 + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the 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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Acute doses and endpoints were not selected for the general U.S. population (including infants and children) or the females 13–50 years old population subgroup for mesotrione; therefore, an acute dietary exposure analysis was not performed.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to mesotrione from food will utilize 1.8% of the cPAD for the U.S. population, 4.3% of the cPAD for

All Infants (< 1 year old) and 4.2% of the cPAD for Children 1–6 years old. There are no residential uses for mesotrione that result in chronic residential exposure to mesotrione.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO MESOTRIONE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0007	1.8	4.3	0.15	24
All infants (< 1 year old)	0.0007	4.3	4.3	0.15	6.7
Children (1–6 years old)	0.0007	4.2	4.3	0.15	6.7
Females (13–50 years old)	0.0007	1.4	4.3	0.15	21

Mesotrione is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

3. *Aggregate cancer risk for U.S. population*. Based on the lack of carcinogenic response in rats and mice and the lack of mutagenic effects, and that there are no data in the literature or SAR information to indicate carcinogenic potential, no cancer risk is posed.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high pressure liquid chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, 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 CODEX, Canadian, or Mexican tolerances/Maximum Residue Levels for mesotrione residues. Thus, harmonization is not an issue at this time.

C. Conditions

Conversion of the mesotrione registration to unconditional under section 3(c)(5) of Federal Insecticide and Fungicide Act (FIFRA) as amended may be considered upon submission of adequate storage stability data in the plant and livestock metabolism studies, revised interference study, developmental neurotoxicity study (DNT) in the mouse, and an 8 day inhalation study.

V. Conclusion

Therefore, the tolerance is established for residues of mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on the raw agricultural commodities field corn grain, field corn forage and field corn stover at 0.01 ppm.

VI. 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–301138 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 August 20, 2001.

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 VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301138, 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).

VII. Regulatory Assessment Requirements

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

VIII. 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 record keeping requirements.

Dated: June 4, 2001.

Joseph Merenda,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Part 180 is amended by adding §180.571 to read as follows:

§ 180.571 Mesotrione; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on the following commodities:

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01

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

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

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

[FR Doc. 01–15614 Filed 6–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301136; FRL–6785–6]

RIN 2070–AB78

L-Glutamic Acid and Gamma Aminobutyric Acid; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of *L*-glutamic acid and gamma aminobutyric acid on all food commodities when applied/used in accordance with good agricultural practices. Emerald BioAgriculture Corporation submitted two petitions to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *L*-glutamic acid and gamma aminobutyric acid.

DATES: This regulation is effective June 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301136, must be received by EPA on or before August 20, 2001.

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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301136 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Carol E. Frazer, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8810; and e-mail address: frazer.carol@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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 Home Page at http://www.epa.gov/. To access this document, on the Home Page 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_00/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–301136. 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, Crystal 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

In the **Federal Register** of December 6, 2000 (65 FR 76241) (FRL–6748–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of two pesticide tolerance petitions by Emerald BioAgriculture Corporation, 3125 Sovereign Drive, Suite B, Lansing, MI 48911–4240. This notice included a summary of the petitions prepared by the petitioner Emerald BioAgriculture Corporation. There were no comments