Commodity	Parts per million
Poultry, mbyp	0.05
Poultry, meat	0.05
Rice, grain	1.50
Rice, hulls	6.00
Rice, straw	2.00
Sheep, fat	1.00
Sheep, mbyp	0.05
Sheep, meat	1.00
Sugarcane	0.60

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301170; FRL–6801–4]

RIN 2070–AB78

Mefenoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of mefenoxam in or on globe artichoke, starfruit, kiwifruit, papaya, black sapote, star apple, canistel, mamey sapote, mango, sapodilla, sugar apple, atemoya, custard apple, lingonberry, fresh herbs, and dried herbs. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The risk assessment performed for mefenoxam is an aggregate risk assessment which includes the proposed new uses of mefenoxam and all current metalaxyl tolerances/uses. Consequently, EPA has reassessed a total of 122 existing tolerances for metalaxyl. By law, EPA is required by August 2002 to reassess 66% of the tolerances in existence on August 2, 1996, or about 6,400 tolerances. The 122 tolerances reassessed in this final rule count toward the August, 2002 review deadline.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301170, must be received by EPA on or before November 16, 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–301170 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@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/. 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_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–301170. 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 August 30, 2000 (65 FR 52746) (FRL–6739–4), EPA issued notices 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 pesticide petitions (PP) 9F05044, 9E06005, and 9E06057 for tolerances by IR-4, Technology Centre of New Jersey, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. These notices included summaries of the petitions prepared by Novartis Crop Protection, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide mefenoxam, (*R*)- and (*S*)-2-[(2,6-dimethylphenyl)-methoxyacetylamino]-propionic acid methyl ester, its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester,

each expressed as mefenoxam equivalents, in or on fresh herb subgroup at 5 part per million (ppm); dried herb subgroup at 30 ppm; fresh mint at 5 ppm; kiwifruit at 0.05 ppm; atemoya, globe artichoke, starfruit, sugar apple, sweepsop, and true custard at 0.1 ppm; papaya, black sapote, caimito, canistel, mamey sapote, mango, and sapodilla at 0.3 ppm; and lingonberry at 1.0 ppm. IR-4 subsequently revised the petitions, deleting tolerances for mint, sweepsop, and caimito; and changing tolerances for fresh herb from 5.0 ppm to 8.0 ppm; dried herb from 30 ppm to 55 ppm; kiwifruit from 0.05 ppm to 0.10 ppm; globe artichoke from 0.1 ppm to 0.05 ppm; atemoya, starfruit, sugar apple, and custard apple from 0.1 ppm to 0.20 ppm; papaya, black sapote, canistel, mamey sapote, mango, and sapodilla from 0.3 ppm to 0.40 ppm; and lingonberry from 1.0 ppm to 2.0 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 these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of mefenoxam on globe artichoke at 0.05 ppm, starfruit at 0.20 ppm, kiwifruit at 0.10 ppm, papaya at 0.40 ppm, black sapote at 0.40 ppm, star apple at 0.40 ppm, canistel at 0.40 ppm, mamey sapote at 0.40 ppm, mango at 0.40 ppm, sapodilla at 0.40 ppm, sugar apple at 0.20 ppm, atemoya at 0.20 ppm, custard apple at 0.20 ppm, lingonberry at 2.0 ppm, fresh herbs at 8.0 ppm, and dried herbs at 55 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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 mefenoxam 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. Metalaxyl is the racemic mixture of the R- and S-enantiomers; mefenoxam is the R-enantiomer. Metalaxyl has an extensive toxicity data base and a Reregistration Eligibility Decision document was completed in September 1994. Data have been accepted by EPA which bridge the necessary environmental fate, chemistry, and toxicology studies from metalaxyl to mefenoxam. The structural similarities between mefenoxam and metalaxyl are the basis for bridging data between the two active ingredients. Mefenoxam and metalaxyl have the same empirical formula, and being optical isomers, differ only in the spatial arrangement of atoms in their structure. Both the R and S enantiomers are considered residues of concern for both chemicals.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents (rats)	NOAEL = 44.8 mg/kg/day LOAEL = 90.5 mg/kg/day based on increased hepatocyte hypertrophy, increased lymphocytic infiltration of liver.
870.3150	90-Day oral toxicity in nonrodents (dogs)	NOAEL = 250 mg/kg/day LOAEL = 1,250 mg/kg/day based on based on increased alkaline phosphatase activity and increased absolute and relative liver weights for both sexes.
870.3200	21-Day dermal toxicity	NOAEL = 1,000 mg/kg/day LOAEL >1,000 mg/kg/day.
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on clinical signs, including post-dose convulsions. Developmental NOAEL = 250 mg/kg/day LOAEL = 400 mg/kg/day based on increased incidence of skeletal variations.
870.3700	Prenatal developmental in nonrodents (rabbits))	Maternal NOAEL = 150 mg/kg/day LOAEL = 300 mg/kg/day based on decreased body weight gain. Developmental NOAEL = 300 mg/kg/day LOAEL > 300 mg/kg/day.

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

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rats)	Parental/Systemic male (M): NOAEL = 62.5 mg/kg/day, female (F): NOAEL = 12.5 mg/kg/day M: LOAEL > 62.5 mg/kg/day, F:LOAEL = 62.5 mg/kg/day based on increased relative liver weights. Reproductive NOAEL = 62.5 mg/kg/day LOAEL > 62.5. Offspring NOAEL = 12.5 mg/kg/day; LOAEL = 62.5 mg/kg/day based on histopathological changes in the livers of female pups.
870.4100	Chronic toxicity dogs	NOAEL = M: 7.80 mg/kg/day, F: 7.41 mg/kg/day; LOAEL = M: 30.63 mg/kg/day, F: 32.36 mg/kg/day based on increased alkaline phosphatase, increased relative and absolute liver weights.
870.4300	Carcinogenicity/chronic toxicity rats	NOAEL = M: 9.43 mg/kg/day, F: 9.95 mg/kg/day; LOAEL = M: 46.6 mg/kg/day, F: 55.0 mg/kg/day based on increased serum alanine amino-transferase and serum aspartate amino-transferase, increased periacinar vacuolation of hepatocytes, increased absolute and relative liver weights. No evidence of carcinogenicity.
870.4300	Carcinogenicity mice	NOAEL = M: 24.85 mg/kg/day, F: 29.59 mg/kg/day; LOAEL = M: 128.89 mg/kg/day, F: 148.16 mg/kg/day based on increased fatty infiltration of the liver. No evidence of carcinogenicity.
870.5100	Gene Mutation	There was no concentration related positive response of induced mutant colonies over background in *Salmonella* or *E. coli* strains.
870.5385	*In vivo* Cytogenetics	Metalaxyl had no effect on the incidence of nuclear anomalies.
870.7485	Metabolism and pharmacokinetics	In the first 8 hours of treatment, approximately 30% of the dose was absorbed with 1% of the test substance in the skin at the application site.
870.7600	Dermal penetration	At 24 hours after dosing, approximately 35% was absorbed.

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.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA 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 1×10^{-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 mefenoxam used for human risk assessment is shown in the following Table 2:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MEFENOXAM 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 general population including infants and children	None	Not applicable	No appropriate study was identified.
Chronic dietary all populations	NOAEL = 7.41 mg/kg/day UF = 100 Chronic RfD = 0.074 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/ FQPA SF = 0.074 mg/kg/day	6-Month Feeding Study in Dogs LOAEL = 32.36 mg/kg/day based on increased liver weights and clinical chemistry.
Short-term dermal (1 to 7 days) (Residential)	None	Not applicable	No systemic toxicity was seen at the limit dose in a 21-day dermal toxicity study in rabbits.
Intermediate-term dermal (1 week to several months) (Residential)	None	Not applicable	No systemic toxicity was seen at the limit dose in a 21-day dermal toxicity study in rabbits.
Long-term dermal (several months to lifetime) (Residential)	NOAEL= 7.41 mg/kg/day UF = 100 Chronic RfD = 0.074 mg/kg/day (dermal absorption rate = 35%)	LOC for MOE = 100 (Residential)	6-Month Feeding Study in Dogs LOAEL = 32.36 mg/kg/day based on increased liver weights and clinical chemistry.
Short-term inhalation (1 to 7 days) (Residential)	oral study NOAEL= 50 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental Toxicity in Rats LOAEL = 250 mg/kg/day based on decreased body weight gains and reduced food consumption.
Intermediate-term inhalation (1 week to several months) (Residential)	oral study NOAEL = 7.41 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	6-Month Feeding Study in Dogs LOAEL = 32.36 mg/kg/day based on increased liver weights and clinical chemistry.
Long-term inhalation (several months to lifetime) (Residential)	oral study NOAEL= 7.41 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	6-Month Feeding Study in Dogs LOAEL = 32.36 mg/kg/day based on increased liver weights and clinical chemistry.
Short-term oral (1 to 7 days) (Residential)	oral study maternal NOAEL = 50 mg/kg/day	LOC for MOE = 100 (Residential)	Developmental toxicity study in rats (mefenoxam). LOAEL = 250 mg/kg/day based on decreased body weight gains and reduced food consumption.
Intermediate-term oral (1 week to several months) (Residential)	oral study NOAEL = 7.41 mg/kg/day	LOC for MOE = 100 (Residential)	6-Month Feeding Study in Dogs (metalaxyl). LOAEL = 32.36 mg/kg/day based on increased liver weights and clinical chemistry (alkaline phosphatase).
Cancer (oral, dermal, inhalation)	None	Not applicable	Based on the classification of metalaxyl,mefenoxam is also considered ''not likely to be a human carcinogen.''

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* A time-limited tolerance has been established (40 CFR 180.546) for the combined residues of mefenoxam, in or on canola (expires December 31, 2001). No other tolerances have been established for mefenoxam *per se*. Since metalaxyl is the racemic mixture of the R- and S- enantiomers; the risk assessment performed for the proposed new uses of mefenoxam includes all current metalaxyl tolerances/uses. Tolerances have been established (40 CFR 180.408) for metalaxyl on various raw agricultural commodities and animal commodities. Tolerances have been established for metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, at 0.4 ppm in the fat, kidney, and liver of cattle, goats, hogs, horses, poultry, and sheep; 0.05 ppm in meat and meat byproducts (except kidney and liver) of cattle, goats, hogs, horses, poultry, and sheep; 0.02 ppm in milk, and 0.05 ppm in eggs. Risk assessments were conducted by EPA to assess dietary exposures from mefenoxam 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. An acute dietary risk assessment was not preformed for mefenoxam since an endpoint of concern was not identified during the review of the available studies.

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 1994–1996 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: Since metalaxyl and mefenoxam share the same residues of concern, the chronic dietary exposure assessment was performed using established metalaxyl tolerances in addition to the proposed tolerances for mefenoxam. The chronic dietary analysis used residue values at the established and recommended tolerance levels, and assumed that 100 percent of the registered and proposed crops were treated. This Tier 1 chronic dietary analysis should be considered highly conservative.

iii. *Cancer*. Metalaxyl has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, based on the classification of metalaxyl, mefenoxam is also considered ''not likely to be a human carcinogen.''

2. *Dietary exposure from drinking water*. Sufficient acceptable bridging data have been submitted to verify that the environmental fate of mefenoxam is similar to that of metalaxyl. Therefore, based on the bridging data submitted (soil photolysis, aerobic soil metabolism and batch equilibrium and column leaching studies), EPA can conclude that environmental fate studies of metalaxyl, including the reviewed studies on mefenoxam, can be used to predict the environmental fate of mefenoxam. Metalaxyl was found to be moderately stable under normal environmental conditions; its degradates are mobile in sandy soils and those low in organic matter. EPA has determined that residues of metalaxyl and mefenoxam and their metabolites *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)alanine (CGA-62826), each expressed as parent equivalents, should be included in the drinking water assessment.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for mefenoxam 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 mefenoxam.

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 Screening Concentrations in Ground Water (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 Percent of the Reference Dose (%RfD) or Percent of the Population Adjusted Dose (%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 mefenoxam they are further discussed in the aggregate risk sections below.

The first-tier screening model GENEEC was used to estimate potential surface water concentrations, and the screening model SCI-GROW was used to estimate potential ground water concentrations. The maximum annual lingonberry application rate of 5.4 lb a.i./acre (2.7 ai/acre twice) was used to model mefenoxam concentrations in drinking water. The GENEEC simulation of the lingonberry use predicts an acute concentration of 180 ppb, and a 90–day chronic concentration of 109 ppb. SCI-GROW modeling simulated mefenoxam concentrations in ground water of 13.5 ppb for this proposed use. For the degradate of concern, CGA-62826, GENEEC modeling results in estimates of 198 ppb for acute exposure and 194 ppb for chronic exposure, with limited environmental fate data. The predicted SCI-GROW concentration for this degradate is 37 ppb in ground water. The combined (parent plus metabolite) EEC values are 101 ppb (109 ppb for parent + 194 ppb for degradate/3) for chronic surface water and 51 ppb (13.5 ppb for parent and 37 ppb for degradate) 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).

Mefenoxam is currently registered for use on the residential non-dietary site turf. Risk assessments were conducted using the following residential exposure assumptions: Residential handler exposure has been assessed for two formulations of mefenoxam: an emulsifiable concentrate, (1) Subdue® MAXX® EC, and (2) a granular, Subdue® MAXX® GR both used at a maximum rate of 0.015 lb ai/1,000 ft^2. Non-occupational (residential) handlers may be exposed during mixing, loading and application of mefenoxam using a variety of application methods for short-term durations (1-7 days) based on the mefenoxam turf use. Continuous exposure over intermediate-term (7 days to several months) or long-term (several months or more) time periods are not expected. Dermal exposure was not assessed because applicable endpoints were not identified. MOEs for inhalation exposure from non-occupational handler scenarios were above the target of 100, and thus do not exceed EPA's level of concern.

Non-occupational postapplication exposures were also assessed for Subdue® MAXX® EC (46.6%) and Subdue® MAXX® GR (0.97%), two

major mefenoxam products on turf which are considered to represent the reasonable upper bound residential exposure potential. Adults and children may be exposed to mefenoxam residues following treatment of residential areas. However, postapplication exposure is limited to incidental oral exposure, since post application inhalation exposure is expected to be negligible and endpoints were not identified for short- or intermediate-term dermal risk assessment. Postapplication exposure assessments were performed for toddler's incidental ingestion of residues of mefenoxam on treated turf (hand-to-mouth, object-to-mouth) and ingestion of granules. MOEs for oral exposure to toddlers were all above 100 and thus do not exceed EPA's level of concern. Also, combined exposure from toddler's incidental ingestion of mefenoxam residues on treated turf and from object-to-mouth exposure from treated turfgrass and soil results in short-term MOEs that are greater than 100 and do not exceed EPA's level of concern.

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 mefenoxam 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, mefenoxam 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 mefenoxam 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. *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.

2. *Conclusion*. There is a complete toxicity data base for mefenoxam and exposure data are complete or are estimated based on data that reasonably account for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because (1) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure, (2) a developmental neurotoxicity study is not required at this time, and (3) the dietary (food and drinking water) and non-dietary exposure assessments will not underestimate the potential exposures for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against 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 ground water are less than the calculated DWLOCs, the Office of Pesticide Programs (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 aggregate risk consists of the combined dietary exposures from food and drinking water sources. The total exposure is compared to the acute RfD. An acute RfD was not identified. Therefore, an acute aggregate risk assessment was not performed.

2. *Chronic risk*. EPA determined that the parent, mefenoxam, and the metabolite *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)alanine (CGA-62826), each expressed as parent equivalents, should be included in the drinking water assessment. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to mefenoxam from food will utilize 17% of the cPAD for the U.S. population, 36% of the cPAD for children 1-6 years old and 14% of the cPAD for females 13-50 years old. Based on the use pattern, chronic residential exposure to residues of mefenoxam is not expected. In addition, there is potential for chronic dietary exposure to mefenoxam in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Ground Water EEC (ppb)	Surface Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.074	17	51	101	2,100
Children 1-6 years	0.074	36	51	101	460
Females 13-50 years	0.074	14	51	101	1,900

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

Mefenoxam is currently registered for use that could result in short-and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short- and intermediate-term exposures for mefenoxam.

Short-term and intermediate aggregate risks from mefenoxam were calculated based on exposures from the oral and inhalation routes of exposure. Inhalation exposure was assessed for the adult, residential pesticide handler only. Postapplication, inhalation exposure to the adult handler is not considered a significant route of exposure. Incidental oral risk was assessed for the postapplication exposure of toddlers in the home environment only. Dermal toxicity endpoints were not chosen for this chemical and thus an assessment of the dermal route of exposure was not performed.

Short- and intermediate-term daily doses from the hand-to-mouth, turfgrass, and soil ingestion pathways were combined and represent the residential exposure potential for toddlers, represented as children 1 to 6 years old. Short- and intermediate-term inhalation values from the residential activity which resulted in the greatest exposure, were used to calculate residential exposures to adult home applicators. In all cases, the residential exposures described above were added to the average food exposures to develop the aggregate exposure estimate. This exposure estimate was then compared to the appropriate toxicity endpoint.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 3,700 for the U.S. population, and 1,300 for children 1-6 years old, and 4,400 for females 13-50 yrs. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of mefenoxam in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO MEFENOXAM

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC(ppb)	Short-Term DWLOC (ppb)
Females 13-50 yrs	4,400	100	101	51	14,000
US Population	3,700	100	101	51	17,000
Children 1-6 yrs	1,300	100	101	51	4,600

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 650 for females 13-50 years old, 560 for the U.S. population, and 230 for children 1-6 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of mefenoxam in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO MEFENOXAM

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Females 13-50 yrs	650	100	101	51	1,900
U.S. population	560	100	101	51	2,100
Children 1-6 yrs	230	100	101	51	420

5. *Aggregate cancer risk for U.S. population*. Metalaxyl has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, based on the classification of metalaxyl, mefenoxam is also considered ''not likely to be a human carcinogen.''

6. *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 mefenoxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method, Method AG-395 (MRID 00148440; sent to FDA for inclusion in PAM II as Method III), is available to determine the regulated residues of mefenoxam i.e., the combined residues of (*R*)-and (*S*)-2-[(2,6-dimethylphenyl)-methoxyacetylamino]-propionic acid methyl ester, its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester, each expressed as mefenoxam equivalents in artichoke, carambola (starfruit), sugar apple, sweetsop, atemoya, true custard apple, kiwifruit, papaya, black sapote, caimito, canistel, mamey sapote, mango, sapodilla, lingonberry, and herbs. Method AG-395 is an improved modification of Method I (Method AG-348) in PAM II. In AG-348, residues are converted to 2,6-dimethylaniline and analyzed by gas chromotography (GLC) with alkali flame ionization detection (AFID). Gas-liquid chromatography/mass spectrometry in the chemical ionization mode with selected ion monitoring is used in the determinative step of Method AG-348 for samples that show interference in the GLC/AFID analysis. In AG-395, residues are converted to 2,6-dimethylaniline and analyzed by gas liquid chromatography (GLC) with a nitrogen/phosphorus detector operating in the nitrogen-specific mode. The limit of quantitation of Method AG-395 is 0.05 ppm for each commodity. Method I in PAM II and Method AG-395 do not distinguish between mefenoxam R-isomer) and metalaxyl which is a mixture of the R and S enantiomers). Method 456-98 can distinguish between R and S enantiomers. A successful EPA method validation has been completed by EPA for Method 456-98.

Adequate enforcement methodology (example: Gas chromotography) 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

No Codex, Canadian, or Mexican Maximum Residue Limits or tolerances have been established for mefenoxam on artichoke, starfruit, kiwifruit, papaya, black sapote, caimito, canistel, mamey sapote, mango, sapodilla, sugar apple, sweetsop, atemoya, true custard apple, lingonberry, or herbs.

C. Rotational Crops

An adequate confined rotational crop study is available on metalaxyl. Based on the metalaxyl confined rotational crop study, EPA has determined that the residues of mefenoxam to be regulated for the tolerance expression and for dietary risk assessments for rotational crops are (*R*)- and (*S*)-2-[(2,6-dimethylphenyl)-methoxyacetylamino]-propionic acid methyl ester, its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester, each expressed as parent equivalents, except that 2-[(methoxyacetyl)(2-methoxy-1-methyl-2-oxoethyl)amino]-3-methylbenzoic acid (CGA-108905) and *N*-(3-hydroxy-2,6-dimethylphenyl)-*N*-(methoxyacetyl)alanine methyl ester (CGA-100255) will be considered in risk assessments involving the foliar use of mefenoxam on the treated crop. EPA concludes that U.S. tolerances are adequate to cover residues on crops grown in rotation with mefenoxam treated crops, provided crop rotation is limited to crops that have established metalaxyl or mefenoxam tolerances. Crop rotational studies are not required for globe artichoke, starfruit, kiwifruit, papaya, black sapote, star apple, canistel, mamey sapote, mango, sapodilla, sugar apple, atemoya, custard apple, lingonberry; it is not reasonably foreseeable that any other food or feed crop will be planted after harvest of these treated crops.

D. Conditions

Registration for use of mefenoxam on papaya and kiwifruit will be conditional. Continued registration will be contingent upon EPA receiving additional residue field trials for papaya and kiwifruit. One additional field trial on kiwifruit from California is required. Additional field trials for papaya are needed from Hawaii and Florida.

V. Conclusion

Therefore, these tolerances are established for the combined residues of mefenoxam, (*R*)- and (*S*)-2-[(2,6-dimethylphenyl)-methoxyacetylamino]-propionic acid methyl ester, its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester, in or on globe artichoke at 0.05 ppm, starfruit at 0.20 ppm, kiwifruit at 0.10 ppm, papaya at 0.40 ppm, black sapote at 0.40 ppm, star apple at 0.40 ppm, canistel at 0.40 ppm, mamey sapote at 0.40 ppm, mango at 0.40 ppm, sapodilla at 0.40 ppm, sugar apple at 0.20 ppm, atemoya at 0.20 ppm, custard apple at 0.20 ppm, lingonberry at 2.0 ppm, fresh herbs at 8.0 ppm, and dried herbs at 55 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–301170 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 November 16, 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–301170, 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). 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 other 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, Agriculturalcommodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 6, 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 180.546 is amended by adding text to paragraph (a) to read as follows:

§ 180.546 Mefenoxam; tolerances for residues.

(a) *General*. Tolerances are established for the combined residues of (*R*)- and (*S*)-2-[(2,6-dimethyl(phenyl)-methoxyacetylamine]-propionic acid methyl ester, and its metabolites containing the 2,6 dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as mefenoxam equivalents, in or on the following food commodities:

Commodity	Parts per million
Artichoke, globe	0.05
Atemoya	0.20
Canistel	0.40
Custard apple	0.20
Herbs, dried	55
Herbs, fresh	8.0
Kiwifruit	0.10
Lingonberry	2.0
Mango	0.40
Papaya	0.40
Sapodilla	0.40
Sapote, black	0.40
Sapote, mamey	0.40
Star apple	0.40
Starfruit	0.20
Sugar apple	0.20

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301172; FRL–6803–2]

RIN 2070–AB78

Bentazon; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of bentazon (3-isopropyl-1H-2,1,3-Benzothiadiazin-4(3H)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on Flax, seed at 1.0 ppm. BASF Corporation, Agricultural Products Division 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 September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301172, must be received by EPA on or before November 16, 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–301172 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. 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 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://