ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301042; FRL–6741–1]

RIN 2070–2078

Mefenoxam; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time–limited tolerance for mefenoxam in or on canola. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on canola. This regulation establishes a maximum permissible level for residues of mefenoxam in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective September 25, 2000. Objections and requests for hearings, identified by docket control number OPP–301042, must be received by EPA on or before November 24, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301041 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dan Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number:(703) 308–9375 and e-mail address: rosenblatt.dan@;epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **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/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301042. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for the seed treatment mefenoxam, in or on canola at 0.05 part per million (ppm). This tolerance will expire and is revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time–limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in

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

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

III. Emergency Exemption for mefenoxam on canola and FFDCA Tolerances

EPA has authorized under FIFRA section 18 the use of mefenoxam on canola seed for control of seed borne diseases in canola seed. EPA was petitioned for the use of a product that contains mefenoxam as one of its active ingredients under section 18 of FIFRA. After having reviewed the submission, EPA granted the emergency use.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of mefenoxam in or on canola. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non–routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on canola after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of mefenoxam and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time–limited tolerance for mefenoxam in or on canola at 0.05 ppm.

Mefenoxam is predominantly the R–enantiomer (94:3 ratio of R– to S–enantiomers) of the racemic mixture of the fungicide metalaxyl. Metalaxyl is a 50:50 combination of the R– and S–enantiomers. In reaching regulatory decisions on mefenoxam, EPA reviewed data which bridges environmental fate, chemistry, and toxicology studies between metalaxyl and mefenoxam. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no observed adverse effects are observed (NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (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 (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD=NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-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. The doses and toxicological endpoints selected and the LOC for margins of exposure for various exposure senarios are summarized in the following Table 1:

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute dietary females 13–50 years of age	None	None	
Acute dietary general population including infants and children	None	None	
Chronic dietary all populations	NOAEL = 7.4 mg/kg/day UF = 100 Chronic RfD = 0.074 mg/kg/day	FQPA SF = 3 cPAD = chronic RfD FQPA SF = 0.025 mg/kg/day	6 month feeding study – dogs LOAEL = 32.4 mg/kg/day based on increased alkaline phosphatase and increased absolute and relative liver weight.
Short–term dermal (1 to 7 days) (1 to 7 days (Residential)	None	None	
Interme diate–term Dermal (1 week to several months) (Residential)	None.	None.	
Long–term dermal (several months to lifetime) (Residential)	dermal (or oral) study NOAEL= 7.4 mg/kg/day (dermal absorption rate = 30% when appropriate)	LOC for MOE = 100 (Residential)	6 month feeding study – dogs LOAEL = 32.4 mg/kg/day based on increased alkaline phosphatase and increased absolute and relative liver weight.
Short–term Inhalation (1 to 7 days) (Residential)	None	None	
Interme diate–term Inhalation (1 week to several months) (Residential)	None	None	
Long–term Inhalation (several months to lifetime) (Residential)	None	None	
Cancer (oral, dermal, inhalation)			The carcinogenicity study in mice and combined chronic toxicity/carcinogenicity study in rats suggest metalaxyl is best considered for EPA Group E (''not likely to be carcinogenic in humans'')

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

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances that permit residues for other registered uses of metalaxyl and mefenoxam have been published at 40 CFR 180.408 on a variety of raw agricultural commodities. Currently, there are no established tolerances for mefenoxam. Risk assessments in support of this action were conducted by EPA to assess dietary exposures from all registered uses of metalaxyl and mefenoxam in food based on the tolerances established at 40 CFR 180.408 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. EPA did not conduct an acute exposure risk assessment for mefenoxam. The rationale for this decision is that the laboratory data on metalaxyl and mefenoxam suggest that no toxic effect could be attributed to a single oral exposure. Therefore, no endpoints were selected for this exposure duration and no risk assessment was conducted.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The risk assessment used the published tolerances for metalaxyl plus the tolerance associated with the requested exemption. Residues were assumed to be at tolerance levels. The use of tolerance level residues is considered a conservative assumption. For agricultural commodities, where such data were available, percent crop treated data were also used.

iii. *Cancer.* EPA bridged data on the carcinogenicity of metalaxyl from a carcinogenicity study in mice and a combined chronic toxicity and carcinogenicity study in rats to assess the carcinogenicity of mefenoxam. Based on these data, mefenoxam is considered ''not likely to be carcinogenic in human.'' This corresponds to category ''E'' in EPA's cancer classification system. Thus, an aggregate cancer risk assessment was not conducted for this action.

iv. *Anticipated residue and percent crop treated information.*

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant sub population group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section

408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State–level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to conditions 2 and 3, regional consumption information and consumption information for significant sub populations is taken into account through EPA's computer–based model for evaluating the exposure of significant sub populations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant sub population group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which metalaxyl or mefenoxam may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for metalaxyl or 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 metalaxyl and 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 SCI–GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening–level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high–end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

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

Since no acute dietary endpoint has been identified, no acute exposure estimated environmental concentrations (EECs) for metalaxyl and mefenoxam in surface water and ground water were calculated. The generic EECs for chronic exposures are estimated to be 63 ppb for surface water, based on the GENEEC model, and 5 ppb for ground water, based on the SCI–GROW model.

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).

Metalaxyl and mefenoxam are currently registered for use on the following residential non–dietary sites: turf and certain ornamental sites. For short–term and intermediate–term exposures, no toxicological endpoint was selected. Thus, no exposure assessment is needed. Chronic, non–dietary, exposure is considered to be 180 days or longer. This sort of exposure duration is not expected to result in association with the requested section 18 exemption. Similarly, chronic non–dietary exposures are not expected from the use of other registered metalaxyl and mefenoxam products. Thus, a quantitative risk assessment for chronic residential exposures was not performed.

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 metalaxyl and 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, metalaxyl and 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 metalaxyl and 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 November 26, 1997 (62 FR 62961).

C. 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies*. EPA has determined that there is adequate information about prenatal developmental toxicity to conclude that mefenoxam and metalaxyl do not pose a risk of increased sensitivity due to *in utero* exposure.

iii. *Reproductive toxicity study*. The 2–generation reproduction study is unacceptable because no offspring or parental toxicity was demonstrated at any dose level. Therefore, reproductive toxicity is currently considered a data gap.

iv. *Prenatal and postnatal sensitivity.* Based on reviewed laboratory data, there is no indication of increased sensitivity as a result of *in utero* exposure. There are no data gaps relative to *in utero* exposure. The 2–generation reproduction study is not considered to be acceptable because toxicity is absent in both offspring and parents at any dose level. This limitation makes it difficult to fully assess the effects of exposure to young animals following early postnatal exposure.

v. *Conclusion*. In considering all of the information in this area, EPA chose to reduce the infant and children's safety factor to 3x for this action. There are several factors underlying this decision: (1) There are no data gaps for this assessment of effects following *in utero* exposure; (2) there is no indication of increased sensitivity of rats and or rabbits to *in utero* exposure to mefenoxam or metalaxyl and ; (3) the exposure assessment will not underestimate the potential dietary and non–dietary exposure resulting from the use of mefenoxam. However, since the reproductive toxicity study is unacceptable the FQPA safety factor is 3x.

D. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to metalaxyl and mefenoxam 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 metalaxyl and mefenoxam on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. As previously stated, no toxic effect was associated with a single dose or exposure to metalaxyl and mefenoxam in laboratory studies. Thus, an acute aggregate risk assessment is not needed.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to metalaxyl and mefenoxam from food will utilize 10% of the cPAD for the U.S. population, 11% of the cPAD for non–nursing infants and 19% of the cPAD for children 1–6 years. Based on the use pattern, chronic residential exposure to residues of the metalaxyl and mefenoxam is not expected. In addition, despite the potential for chronic dietary exposure to these pesticides in drinking water, after calculating the DWLOCs and comparing them to conservative model estimated environmental concentrations of metalaxyl and mefenoxam in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON–CANCER) EXPOSURE TO MEFENOXAM

Population Subgroup	cPAD mg/kg/day	cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.25	10%	63 ppb	5 ppb	780
children 1–6 years	0.25	19%	63 ppb	4.95 ppb	200
non–nursing infants	0.25	11%	63 ppb	4.95 ppb	220

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

Though residential exposure could occur with the use of metalaxyl and mefenoxam, no toxicological effects have been identified for short–term toxicity. Therefore, the aggregate risk is

the sum of the risk from food and water, which were previously addressed.

4. *Intermediate–term risk*. Intermediate–term aggregate exposure takes into account non–dietary, non–occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of metalaxyl and mefenoxam, no toxicological effects have been identified for intermediate–term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. An aggregate cancer risk was not conducted for this action. Available data on metalaxyl and mefenoxam indicate that the chemical is considered ''not likely to be carcinogenic in humans.''

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Enforcement methodology to enforce residues associated with this use on agricultural and animal commodities for metalaxyl is available in the Pesticide Analytical Manual. A unique method for mefenoxam, predominantly the R–enantiomer of metalaxyl, is under review at this time.

B. International Residue Limits

At this time, there are no Codex, Canadian, or Mexican residue tolerances for mefenoxam on canola. However, EPA is coordinating with the Canadian pesticide regulatory agency on this matter where a permit for the use of Helix on canola is under review. Thus, this time–limited tolerance for mefenoxam is expected to be compatible with future actions by Canadian officials on this matter.

C. Magnitude of Residues

Residues of mefenoxam (R)-2-[(2,6-dimethylphenyl)-methoxyacetylamino-propionic acid methyl ester and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester each expressed as mefenoxam equivalents are not expected to exceed 0.05 ppm in/on canola seed or its processed commodities (meal and refined oil) as a result of this section 18 use.

Secondary residues of mefenoxam in animal commodities as a result of this section 18 use are not expected to exceed the established tolerance for metalaxyl: 0.05 ppm for meat and meat byproducts (except kidney and liver) of cattle, goats, hogs, horses, poultry, and sheep; 0.4 ppm for fat, kidney, and liver of cattle, goats, hogs, horses, poultry, and sheep; 0.02 ppm for milk; and 0.05 ppm for eggs.

VI. Conclusion

Therefore, the tolerance is established for mefenoxam,, in or on canola at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301042 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 24, 2000.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301042, 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 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* October 4, 1993 (58 FR 51735). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* May 19, 1998, (63 FR 27655) special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low–Income Populations* February 16, 1994 (59 FR 7629) or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* April 23, 1997 (62 FR 19885). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the 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* August 10, 1999 (64 FR 43255). 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).

IX. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 11, 2000.

Susan B. Hazen,

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), (346a) and 371.

2. Section 180.546 is added to read as follows:

§ 180.546 Mefenoxam; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* A time–limited tolerance is established for mefenoxam (R)-2-(2,6-dimethylphenyl)-methoxyacetylamino-propionic acid methyl ester and 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 the following commodities food in connection with the use of the pesticide under a section 18 exemption granted by EPA. The time–limited tolerance will expire on the date specified in the following Table:

Commodity	Parts per million	Expiration/revocation date
Canola	0.05	12/31/01

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

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

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket 99–231; FCC 00–312]

Spread Spectrum Devices

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Commission's rules for frequency hopping spread spectrum devices in the 2.4 GHz band (2400–2483.5 MHz). The rules were amended to allow frequency hopping spread spectrum transmitters operating in the band to use a minimum of 15 hopping channels, spanning a total of 75 MHz. The new rules will allow for hopping channels up to 5 MHz wide. The wider bandwidths will permit these systems to provide higher data speeds, thereby enabling the development of new and improved consumer products such as wireless computer local area networks and wireless cable modems.

DATES: Effective September 25, 2000.

FOR FURTHER INFORMATION CONTACT: Neal L. McNeil, Office of Engineering and Technology, (202) 418–2408, TTY (202) 418–2989, e-mail: nmcneil@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *First Report and Order,* ET Docket 99–231, FCC 00–312 adopted August 24, 2000 and released August 31, 2000. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center, (Room CY–A257) 445 12th Street SW., Washington, DC. The complete text of this document also may be purchased from the Commission's duplication contractor, International Transcription Service, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

Summary of Report and Order

1. The First Report and Order (''R&O'') amends the Commission's rules for frequency hopping spread spectrum devices in the 2.4 GHz band (2400–2483.5 MHz). The rules were amended to allow frequency hopping spread spectrum transmitters operating in the band to use a minimum of 15 hopping channels, spanning a total of 75 MHz. The new rules will allow for hopping channels up to 5 MHz wide. The wider bandwidths will permit these systems to provide higher data speeds, thereby enabling the development of new and improved consumer products such as wireless computer local area networks and wireless cable modems.

2. The Commission initiated a Notice of Proposed Rule Making (''Notice''), 64 FR 38877, July 20, 1999, in this proceeding in response to a letter filed by the Home RF Working Group (''Home RF'') requesting that part 15 spread spectrum systems operating in the 2.4 GHz band be permitted to use bandwidths of up to 5 MHz. The Notice proposed rule changes consistent with the request of the Home RF Working Group. Specifically, the Notice proposed to allow systems to operate with bandwidths of up to 3 MHz or 5 MHz in the 2.4 GHz band. Under the proposal, the systems would utilize 75 hopping channels. Output power would be reduced in proportion to the increase in bandwidth over 1 MHz. For example, systems with 3 MHz bandwidths would operate with output power of no more than 320 mW and channel occupancy time no greater than 0.05 second per hop. Each of the 75 channels would be used at least once during a 3.75 second period. Like existing 1 MHz systems, the average time of occupancy on any channel would not be greater than 0.4 second within a 30 second period. Under the proposal, systems using 5 MHz bandwidths would operate with output power of no more than 200 mW and channel occupancy time of no greater than 0.02 second per hop. Each of the 75 hopping channels would be used at least once during a 1.5 second period. Again, the average occupancy time on any channel would remain 0.4 second or less per 30 second period.

3. Opponents of the proposed rules expressed a number of concerns. For example, the Wireless Ethernet Compatibility Alliance (''WECA'') filed comments October 14, 1999, asserting that devices operating under the proposed new rules will not be able to achieve the claimed higher data rates because they will be more prone to multipath and interference problems. The opponents therefore assert the Home RF proposal will have little or no public benefit. The opponents are concerned that, under the Notice, wide band frequency hopping systems could use overlapping hopping channels. Intersil and Lucent submitted technical analyses and test data claiming to show that interference from partially overlapping channels is more detrimental to frequency hopping systems than the first-adjacent or co-channel interference. According to Intersil, wide band frequency hopping systems employing overlapping channels will experience a greater level of mutual interference than existing systems that use 1 MHz bandwidths. To compensate, they assert that the systems would likely resort to multiple retransmissions, with the net effect that wide bandwidth systems will transmit continuously and totally occupy the 2400–2483 MHz band to the exclusion of other devices. Silicon Wave supports Intersil's findings. Several parties state that the Home RF proposal will cause interference to devices under development by Bluetooth, a cross-industry group formed to establish industry-wide specifications for unlicensed wireless voice and data communications devices operating in the 2.4 GHz band

4. WECA and other opponents of the Home RF proposal offer several proposals as a compromise to reduce the potential for interference to other part 15 devices. They maintain that the output power should be reduced much further than the proposed 200 milliwatts. Several members of WECA offer a compromise that would limit the bandwidth of wide band frequency hopping spread spectrum systems to 4 MHz, establish a minimum of 20 hopping channels, and restrict the output power to 65 milliwatts. WECA asserts that this proposal would be consistent with European standard ETS 300 328. The ETS 300 328 standard permits frequency hopping systems in the 2.4 GHz band to use at least 20 non-overlapping hopping channels, each with up to 4 MHz bandwidth, and up to 100 mW effective radiated power, or 61 mW transmitter output power based on an assumed antenna gain of 1.64. WECA notes that, in a previous proceeding where the Commission reduced the number of required hops for spread spectrum devices operating in the 915 MHz band, the output power was reduced in proportion to the square in the number of hopping frequencies. For a system using a 4 MHz bandwidth the number of hopping channels would be reduced by a factor of approximately 4 (from 75 to 20 channels), and the output power would need to be reduced by a factor of 16 (from 1 watt to 60 mW). WECA also suggests two additional requirements. First, WECA proposes to require interference rejection tests for receivers in frequency hopping systems having channel widths greater than 1 MHz. WECA states that the test is necessary to ensure that receiver performance is adequate to minimize the need to retransmit packets, which,