(115) On July 31, 2003, the State of Colorado submitted revisions to Colorado's 5 CCR 1001–3, Regulation 1, that deleted Sections II.A.6, A.7, A.9 and C.3, regarding, respectively, alfalfa dehydrating plant drum dryers, wigwam burners, the static firing of Pershing missiles and a notice regarding waste materials. The State also deleted emission limitations for alfalfa plant drum dyers by removing Section III.C.2. Colorado's deletion of Sections II. A6, A.7 and A.9 and Section III.C.2 will cause a numbering change of subsequent paragraphs within Sections II.A and III.C. EPA is adopting the new numbering scheme for sections II.A. and III C. Section II.C.2.d. regarding agricultural open burning is modified to include the burning of diseased animal carcasses to prevent a public health emergency. Section III.A.1.d is modified for incorporation of new State's method for calculating emissions from multiple fuel burning units ducted to a common stack. Section V is added regarding emission standards for electric arc furnaces, except for the director's discretion provision provided for in Section V.A.2. Sections VI.A.3.e, VI.A.3.f, VI.B.4.e, and VI.B.4.g(ii) are modified regarding the methods used for the averaging of emissions over a 24 hour period.

(i) Incorporation by reference.

(A) 5 CCR 1001–3, Regulation 1, Emission Control for Particulates, Smokes, Carbon Monoxide and Sulfur Oxides, Section II, Smoke and Opacity, Section II.C.2.d, effective March 2, 2002.

(B) 5 CCR 1001–3, Regulation 1, Emission Control for Particulates, Smokes, Carbon Monoxide and Sulfur Oxides, Section III, Particulate Matter, Fuel Burning Equipment, Section III.A.1.d, effective September 30, 2001.

(C) 5 CCR 1001–3, Regulation 1, Emission Control for Particulates, Smokes, Carbon Monoxide and Sulfur Oxides, Section V, Emission Standard for Existing Iron and Steel Plant Operations, effective September 30, 2001.

(1) The submittal contains Section V.A.2 with the language:

"Emissions from gas-cleaning device shall not exceed a mass emission rate of 0.00520 gr/dscf of filterable particulates maximum two-hour average, as measured by EPA Methods 1–4 and the front half of Method 5 (40 CFR 60.275, and Appendix A, Part 60), or by other credible method approved by the Division. This particulate emissions standard does not include condensable emissions, or the back half emissions of Method 5". The language "or by other credible method approved by the Division" is disapproved. The language "Appendix A, Part 60" is changed to "appendices A1 through A3, Part 60" in order to comply with the current nomenclature of Part 60.

(D) 5 CCR 1001–3, Regulation 1, Emission Control for Particulates, Smokes, Carbon Monoxide and Sulfur Oxides, Section VI, Sulfur Dioxide Emission Regulations, Sections VI.A.3.e, VI.A.3.f, VI.B.4.e, and VI.B.4.g(ii), effective September 30, 2001.

(1) Sections VI.B.4.e and VI.B.4.g(ii) list an emission rate of 0.7 lbs. sulfur dioxide, for the sum of all SO_2 emissions from a given refinery per barrel of oil processed, per day. This emission rate is disapproved. The emission rate remains unchanged at 0.3 lbs. All remaining language within Sections VI.B.4.e and VI.B.4.g(ii) is approved.

[FR Doc. 2011–1497 Filed 1–25–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0713; FRL–8855–1]

Mefenoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefenoxam in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes the individual tolerance on lingonberry, as it will be superseded by inclusion in bushberry subgroup 13–07B. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 26, 2011. Objections and requests for hearings must be received on or before March 28, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see* also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0713. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7509P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0713 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 28, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0713, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-for Tolerances

In the **Federal Register** of October 7, 2009 (74 FR 51597) (FRL–8792–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7591) by IR–4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.546 be amended by establishing tolerances for residues of the fungicide mefenoxam, (*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 bean, snap, succulent at 0.35 parts per million (ppm); caneberry subgroup 13–07A at 0.80 ppm; bushberry subgroup 13–07B at 2.0 ppm; onion, bulb, subgroup 3–07A at 3.0 ppm; onion, green, subgroup 3–07B at 10.0 ppm; and spinach at 8.0 ppm. The notice additionally requested to remove the individual tolerance for lingonberry at 2.0 ppm, as it will be superseded by inclusion in bushberry subgroup 13–07B. That notice referenced a summary of the petition prepared on behalf of IR–4 by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. EPA has also revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for mefenoxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mefenoxam 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.

Mefenoxam, is the *R*-enantiomer of metalaxyl which is a racemic mixture that contains approximately 50% each of the *R*- and *S*-enantiomers. EPA conducted a side-by-side comparison of the available toxicity data for mefenoxam and metalaxyl and concluded that mefenoxam has similar toxicity to that of metalaxyl. Therefore, metalaxyl data may be used to support the registration of mefenoxam.

The database for mefenoxam/metalaxyl indicates that the liver is the major target organ. Liver effects observed in oral studies in rats, mice, and dogs include increased liver enzymes (alanine amino-transferase, aspartate amino-transferase, and alkaline phosphatase), increased incidence of pathological observations in the liver (hepatocyte hypertrophy, vacuolation of hepatocytes, and fatty infiltration) and increased relative and absolute liver weights. In guideline studies, the dog appears to be the most sensitive species.

The developmental toxicity studies in rat and rabbit and the multigeneration reproduction study did not show metalaxyl/mefenoxam to be a developmental or reproductive toxicant. There was no indication of increased susceptibility in pups following prenatal and postnatal exposures to mefenoxam. In the rat and rabbit developmental toxicity studies, in which animals were administered metalaxyl by gavage at relatively high doses, both rat and rabbit dams exhibited clinical signs (ataxia, body tremors, reduced activity, and righting reflex). These clinical signs are believed to result from metalaxyl/mefenoxam induced bradycardia mediated through alpha-adrenoreceptors and not from neurotoxicity.

Metalaxyl has been classified as "not likely to be carcinogenic to humans" based on the results of a carcinogenicity

study in mice and the combined chronic toxicity and carcinogenicity studies in rats. Based on the classification of metalaxyl, mefenoxam is also considered "not likely to be carcinogenic to humans." Mutagenicity studies do not indicate increased mutagenic potential following exposure to metalaxyl/mefenoxam.

Specific information on the studies received and the nature of the adverse effects caused by mefenoxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Mefenoxam. Human Health Risk Assessment for Proposed Uses on Snap Beans and the Caneberry Subgroup, Expanded Uses on the Bulb and Green Onion Subgroups and the Bushberry Subgroup, and Amended Use on Spinach." at pages 51–53 in docket ID number EPA–HQ–OPP–2009–0713.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level–generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)–and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for mefenoxam used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age and the general population including infants and children).	None. No appropriate endpoint attributable to a single dose was identified.		
Chronic dietary (All populations)	NOAEL = 7.41 mg/kg/day, UF_A = 10x, UF_H = 10x, FQPA SF = 1x.	Chronic RfD = 0.074 mg/kg/day. cPAD = 0.074 mg/kg/day.	6-Month Feeding (Metalaxyl) Study in Dog, LOAEL = 39 mg/kg/day, based on increased liver weights and clinical chemistry (alkaline phosphatase).
Incidental oral short-term (1 to 30 days)	NOAEL = 50 mg/kg/day, UF_A = 10x, UF_H = 10x, FQPA SF = 1x.	LOC for MOE = 100.	Developmental Toxicity in Rat (Metalaxyl), LOAEL = 250 mg/kg/day based on clinical signs of toxicity including post-dosing convulsions.
Incidental oral intermediate-term (1 to 6 months).	NOAEL = 7.41 mg/kg/day, UF_A = 10x, UF_H = 10x, FQPA SF = 1x.	LOC for MOE = 100.	6-Month Feeding (Metalaxyl) Study in Dog, LOAEL = 39 mg/kg/day based on increased liver weights and clinical chemistry (alkaline phosphatase).
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL = 50 mg/kg/day (inhalation absorption rate = 100%), UF_A = 10x, UF_H = 10x, FQPA SF = 1x.	LOC for MOE = 100.	Developmental Toxicity in Rat (Metalaxyl), LOAEL = 250 mg/kg/day based on clinical signs of toxicity including post-dosing convulsions.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies).
UF_H = potential variation in sensitivity among members of the human population (intraspecies).
FQPA SF = Food Quality Protection Act Safety Factor.
PAD = population adjusted dose (a = acute, c = chronic).
RfD = reference dose.
MOE = margin of exposure.
LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to mefenoxam, EPA considered exposure under the petitioned-for tolerances as well as all existing mefenoxam tolerances in 40 CFR 180.546 and metalaxyl tolerances in 40 CFR 180.408. EPA assessed dietary exposures from mefenoxam/metalaxyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies

for mefenoxam; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues for most commodities. Additional factors derived from available residue chemistry data were applied to the tolerance values for leafy vegetables, grain seed (including dried beans), with the exception of flour cereal grains, nut commodities, succulent snap beans, and caneberries to address concerns regarding the adequacy of the residue analytical method to determine all metalaxyl/mefenoxam residues of concern, including metabolites, in plant and animal commodities. This was accomplished by calculating parent and metabolite to parent ratios to residue levels of concern for risk assessment purposes.

Additionally, EPA used DEEM default processing factors except where specific mefenoxam/metalaxyl tolerances exist for processed commodities or where metabolism and processing data are available to establish specific processing factors. Tolerances were used for dried apricot, tomato paste, tomato puree, and potato processed commodities and a data-derived processing factor was applied for fruit juices based on available metabolism and processing data. Finally, the dietary assessment incorporated average percent crop treated (PCT) information, when available, for mefenoxam because it showed higher estimates than metalaxyl. One hundred PCT was used for all other commodities, including the proposed uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that mefenoxam does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Almond, 1%	Honeydew, 5%
Apple, 1% 5%	Lemon, 5%
Artichoke; 5%	Lettuce, 10%
Asparagus, 10%	Onion, 30%
Avocado, 2.5%	Orange, 5%
Blueberry, 1%	Peach, 1%
Broccoli, 10%	Peanut, 1%
Cabbage, 10%	Pea, green, 2.5%
Cantaloupe, 10%	Pepper, 15%
Tomato, 15%	Potato, 20%
Carrot, 35%	Pumpkin, 5%
Cauliflower, 5%	Rice, 1%
Celery, 5%	Soybean, 10%
Cherry, 1%	Squash, 10%
Cotton, 5%	Strawberry, 10%
Cucumber, 10%	Sugar beet, 1%
Dry bean and pea, 1%	Sweet corn, 1%
Garlic, 15%	Tangerine, 10%
Grapefruit, 5%	Walnut, 1%
Grape, 1%	Watermelon, 15%

In most cases, EPA uses available data from the USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations 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 subpopulation 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 reliable information on the regional consumption of food to which mefenoxam may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for metalaxyl/mefenoxam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mefenoxam. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Tier I Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of mefenoxam for chronic exposures for non-cancer assessments are estimated to be 36.7 parts per billion (ppb) for surface water and 1.72 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 36.7 ppb was used to assess the contribution to drinking 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 the following uses that could result in residential exposures: Residential turf and ornamentals and recreational turf,

such as golf courses and athletic fields. EPA assessed residential exposure using the following assumptions: Exposure to adults may occur from handling mefenoxam, and to children from postapplication contact with treated areas. Therefore, adult handlers were assessed for short-term inhalation exposure resulting from residential application of mefenoxam; intermediate-term handler exposure is not expected. For children, short- and intermediate-term postapplication oral exposures (hand-to-mouth, object-to-mouth, and incidental ingestion of soil) were assessed. Dermal toxicity endpoints were not identified for any mefenoxam use pattern and chronic residential exposure is not expected; therefore, these exposure scenarios were not assessed. It was also determined that postapplication mefenoxam exposures to adults and children at recreational use sites would be similar to those assessed for residential use sites and, therefore, a separate recreational exposure assessment is not necessary.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

EPA has not found mefenoxam to share a common mechanism of toxicity with any other substances, and mefenoxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that mefenoxam does not have 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 EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence that mefenoxam results in increased susceptibility from *in utero* exposure to rats or rabbits in the prenatal developmental studies or exposure to young rats in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for mefenoxam is complete except for immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 require acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200), and immunotoxicity testing (OPPTS Guideline 870.7800) for pesticide registration. However, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. The available studies do not indicate potential for immunotoxicity, as evidenced by the lack of effects seen in the spleen, thymus, or hematological parameters. Also, metalaxyl and mefenoxam do not belong to a class of compounds (*e.g.,* the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be toxic to the immune system.

ii. With respect to neurotoxicity, clinical signs (ataxia, body tremors, reduced activity, and righting reflex) were observed in maternal animals in rat and rabbit developmental studies at relatively high doses (≥ 150 mg/kg/day), where metalaxyl was administered by gavage only. These clinical signs were unlikely neurotoxically mediated, but rather resulted from the bradycardia mediated through alpha-adrenoreceptors. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that mefenoxam results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. Although one additional field trial with residue decline measures is needed to complete the geographic distribution for caneberry crops, there are no uncertainties in the exposure database due to the fact that: (1) There is no significant difference in residues in blackberry/raspberry samples from field trials conducted in four regions including the major production region (~70%) and relatively low production (6–15%) in the remaining regions; and (2) existing decline data indicate that residues decline with increasing sampling intervals.

The chronic dietary food exposure assessment was somewhat refined, using estimated average PCT data, when available, and 100 PCT for all other commodities. The assessment was also performed based on tolerance-level residues or additional factors to address concerns regarding the adequacy of the residue analytical method in some commodities and DEEM default processing factors unless specific tolerances were established for processed commodities or metabolism and processing data were available to establish specific processing factors. These assumptions are based on reliable data which will not underestimate potential dietary exposures. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to mefenoxam in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by mefenoxam.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was

selected. Therefore, mefenoxam is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to mefenoxam from food and water will utilize 60% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of mefenoxam is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Mefenoxam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to mefenoxam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,500 for the general U.S. population; 920 for children 3–5 years old; and 880 for children 1–2 years old. Because EPA's level of concern for mefenoxam is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Mefenoxam is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to mefenoxam.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 150 for children 3–5 years old and 140 for children 1–2 years old. Because EPA's level of concern for mefenoxam is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, mefenoxam is not expected to pose a cancer risk to 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, or to infants and children from aggregate exposure to mefenoxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

For the purposes of this tolerance action, adequate enforcement methodologies including a gas-liquid chromatography with alkali flame-ionization detection (GLC/AFID) (Method AG–348) and a GLC with nitrogen-phosphorus detection (NPD) (Method AG–395) are available to enforce the tolerance expression for plant commodities. However, the Agency determined that the current residue analytical methods available for tolerance enforcement will not adequately recover all of the metalaxyl/mefenoxam residues of concern in the revised tolerance expression. For this action, therefore, the Agency applied additional factors derived from available residue chemistry data to certain commodities to account for all residues of concern for dietary risk assessments, as previously described in Unit III.C.ii.

Neither Method AG–348 nor Method AG–395 distinguish between the *R*- and *S*-enantiomers of metalaxyl/mefenoxam; however, a confirmatory high performance liquid chromatography method with mass spectrometric detection that utilizes a chiral column (chiral LC/MS), Method 456–98, is available for the enantioselective determination of the *D*- and *L*-enantiomers of metalaxyl in crops. Therefore, EPA has determined for future actions that the multiresidue method Protocol D, which completely recovers metalaxyl/mefenoxam *per se,* is an adequate enforcement method for the determination of metalaxyl/mefenoxam *per se* in plant and livestock commodities; and analysis using a 2,6–DMA common moiety method, including recovery data for parent, CGA-62826, and CGA-94689, can be used in order to refine dietary risk assessments.

Method AG–;348 may be found in PAM Vol. II; Method AG–395 and Method 456–98 have been submitted for inclusion in PAM Vol. II; and Multiresidue method Protocol D may be found in PAM, Vol. I Section 302. Methods not published in PAM may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Pending revocation of Codex MRLs for metalaxyl, Codex MRLs for metalaxyl-m (mefenoxam) have not been advanced to final status. Therefore, there are currently no Codex MRLs established for residues of mefenoxam in or on the commodities associated with this petition. However, with the adoption of the revised tolerance expression, the U.S. tolerance expression will be harmonized with the tolerance expression for Codex.

Canadian MRLs for mefenoxam (metalaxyl-m) are covered by MRLs established for metalaxyl, and Canadian MRLs have been established for residues of metalaxyl in or on spinach at 10 ppm, bulb onion at 3.0 ppm, green onion at 10 ppm, bean at 0.2 ppm, raspberry at 0.2 ppm, and blueberry at 2.0 ppm. The Canadian MRLs are harmonized with U.S. tolerance levels in or on the commodities associated with this petition, with the exception of caneberry subgroup 13–07A, which is being established at 0.70 ppm (the Canadian MRL for raspberry is 0.2 ppm). The U.S. tolerance on caneberry subgroup 13–07A cannot be harmonized with the Canadian MRL on raspberry at this time because the field trial data supporting the U.S. tolerance result in residues above 0.2 ppm. Additionally, with the adoption of the revised tolerance expression for mefenoxam, the U.S. tolerance expression will not be in harmonization with Canadian MRLs.

C. Revisions to Petitioned-for Tolerances

Based on analysis of the residue field trial data supporting the petition, EPA revised the proposed tolerances on bean, snap, succulent from 0.35 ppm to

0.20 ppm; caneberry subgroup 13–07A from 0.80 ppm to 0.70 ppm; and spinach from 8.0 ppm to 10 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.* Additionally, EPA has revised the tolerance expression to clarify: (1) That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of mefenoxam not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of mefenoxam, including its metabolites and degradates, in or on bean, snap, succulent at 0.20 ppm; caneberry subgroup 13–07A at 0.70 ppm; bushberry subgroup 13–07B at 2.0 ppm; onion, bulb, subgroup 3–07A at 3.0 ppm; onion, green, subgroup 3–07B at 10 ppm; and spinach at 10 ppm. Compliance with the specified tolerance levels is to be determined by measuring only metalaxyl (methyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-*DL*-alaninate). Additionally, this regulation deletes the individual tolerance in or on lingonberry at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.,* 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: January 13, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.546 is amended by revising paragraph (a) introductory text; removing the entry for "Lingonberry" from the table; and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.546 Mefenoxam; tolerances for residues.

(a) *General.* Tolerances are established for residues of mefenoxam, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only metalaxyl (methyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-*DL*-alaninate).

Commodity	Parts per million
* * * * *	
Bean, snap, succulent	0.20
Bushberry subgroup 13–07B	2.0
Caneberry subgroup 13–07A	0.70
* * * * *	
Onion, bulb, subgroup 3–07A	3.0
Onion, green, subgroup 3–07B	10
* * * * *	
Spinach	10
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[FR Doc. 2011–1655 Filed 1–25–11; 8:45 am]

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