Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

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: August 23, 2006.

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 180.368 is amended in paragraph (a)(3) by adding commodities to the table to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a)* * *

(3) * * *

Commodity	Parts per million
* * *	* *
Pumpkin	0.1
* * *	* *
Squash, winter	0.1
* * *	* *

* * * * *

[FR Doc. E6–14443 Filed 8–29–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0537; FRL–8086–2]

Ethofumesate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the herbicide, ethofumesate in or on carrot, roots (with regional restrictions for use in the States of Washington and Oregon), beet, garden, tops and beet, garden, roots; onion, bulb; garlic, bulb; shallot, bulb; and shallot, fresh leaves. The Interregional Research Project #4 (IR-4), 681 Highway 1 South, North Brunswick, NJ 08902–3390 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 30, 2006. Objections and requests for hearings must be received on or before October 30, 2006, 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–2005–0537. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

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. 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–2005–0537 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 October 30, 2006.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2005–0537, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of March 22, 2006 (71 FR 14522) (FRL–7767–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of (pesticide petitions (PP) 3E6564, 3E6565 and 5E6914) by IR-4, 681 Highway 1 South, North Brunswick, NJ 08902–3390 on behalf of the registrant, Bayer CropScience. The petition requested that 40 CFR 180.345 be amended by establishing tolerances for combined residues of the herbicide ethofumesate (2-ethoxy -2, 3-dihydro-3, 3-dimethyl-5-benzofuranyl methanesulfonate) and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate (both calculated as the parent compound) in or on the raw agricultural commodities: Carrots (with regional restrictions for use in the States of Washington and Oregon) at 10 parts per million (ppm) (PP 3E6565), garden beets tops at 4 ppm, garden beet roots at 0.5 ppm (PP 3E6564), onion, dry bulb at 0.30 ppm (PP 5E6914), garlic, bulb at 0.30 ppm (PP 5E6914), and shallot at 0.30 ppm (PP 5E6914). That notice included a summary of the petitions prepared by Bayer CropScience, P. O. Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709, the registrant. There were no comments received in response to the notice of filing.

Supporting documents including the Reregistration Eligibility Decision (RED) for Ethofumesate, EPA 738-R-05-010, Sept. 2005, can be viewed on-line along with the Agency's Human Health Risk Assessment of ethofumesate and other supporting documents at *www.regulations.gov* under the index of the docket for this action, Docket ID number: EPA–HQ–OPP–2005–0537. The Agency's reregistration and tolerance reassessment of ethofumesate are completed. Due to its uses, risks, and other factors, ethofumesate was reviewed/reassessed through the modified 4-Phase process as outlined in the **Federal Register** on May 14, 2004 (69 FR 26819)(FRL–7357–9). Through this process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for ethofumesate.

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....''

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 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of ethofumesate on: Carrot (with regional restrictions for use in Washington and Oregon) at 7.0 ppm, beet, garden, tops at 4.0 ppm, beet, garden, roots at 0.5 ppm, onion, dry bulb at 0.25 ppm, garlic, bulb at 0.25 ppm, and shallot at 0.25 ppm. It can be noted that the tolerance level for certain commodities was revised, based on current data evaluations and differ from the proposed level presented in the Notice of Filing on March 22, 2006 or as recommended in the RED for ethofumesate. These revisions include: Carrot tolerance at 7.0 ppm, reduced from 10.0 ppm; and garlic, bulb; onion, dry bulb and shallot tolerances set at 0.25 ppm, reduced from 0.30 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the toxic effects caused by ethofumesate 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 *www.regulations.gov*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for ethofumesate used for human risk assessment can be found in the index of this document, Docket ID number EPA–HQ–OPP–2005–0537, entitled, ''Human Health Risk Assessment for Proposed Uses on Onion, Bulb'', (Table 3.4.15) (dated April 24, 2006).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.345 for the combined residues of ethofumesate, in or on a variety of raw agricultural commodities; plant commodities range from 0.1 ppm in/on sugar beet roots to 1.0 ppm in/on sugar beet tops and grass straw. Tolerances on animal commodities including fat, meat and meat byproducts are set at 0.05 ppm. A process feeds tolerance in sugar beet molasses is set at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from ethofumesate 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 appropriate endpoint was identified for the general population and infants since no such effects were identified in the toxicological studies for ethofumesate; therefore, a quantitative acute dietary exposure assessment was not conducted for these populations. For females, 13 plus years of age, in conducting the acute dietary (food + water) exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID(™) Version 2.03), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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 acute exposure assessments: A conservative acute dietary assessment was performed using tolerance level residues and 100 % crop treated (PCT) in the assessment.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™. The following assumptions were made for the chronic exposure assessments: A conservative chronic dietary (food + water) assessment was performed using tolerance level residues and 100 PCT.

iii. *Cancer*. Ethofumesate is classified as ''not likely to be a human carcinogen,'' based on bioassays in the rat and the mouse. An exposure assessment for the purpose of assessing cancer risk is not needed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for ethofumesate 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 ethofumesate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found *http://www.epa.gov/oppefed1/models/water/index*. Typically EPA evaluates the potential for human exposure to pesticides in drinking water through an assessment of available surface water and ground water monitoring data and modeling.

For ethofumesate, no monitoring data were available for use in this drinking water assessment. Therefore, potential human exposures to ethofumesate were evaluated through modeling. Estimated exposure concentrations (EECs) in surface water were calculated using Pesticide Root Zone Model/Exposure Analyses Modeling System (PRZM/EXAMS). Ground water concentrations were modeled using screening concentration in ground water (SCI-GROW) (version 2.3). Drinking water residues were then incorporated into the DEEM-FCID(™) into the food categories ''water, direct, all sources'' and ''water, indirect, all sources.'' The Agency concluded that degradates of ethofumesate are of toxicological equivalence to the parent. Because these degradates were detected in environmental fate studies in relatively low amounts (10%), only the parent needs to be assessed for drinking water.

Based on the PRZM/EXAMS - Index Reservoir and SCI-GROW models, the estimated environmental concentrations (EECs) of ethofumesate for acute exposures are estimated to be 154 parts per billion (ppb) for surface water and 8.4 ppb for ground water. The EECs for chronic exposures are estimated to be 45.5 ppb for for surface water and 8.4 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For the acute assessment, the peak concentration of 154 ppb was used to access the contribution to drinking water; for the chronic assessment, the annual mean value of 45.5 ppb was used to access 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).

Ethofumesate is currently registered for use on the following residential non-dietary sites: Turf grasses/lawns. The risk assessment was conducted using the following residential exposure assumptions: All ethofumesate products are intended for either agricultural use or require professional application for ornamental turf. For potential ethofumesate residential post-application exposure, the Agency conducted screening level calculations on the scenarios most likely to result in highest possible exposure to this herbicide. The other aspects of the turf exposure scenario involve calculating dose from non-dietary ingestion that arises from the hand-to-mouth, object-to-mouth and soil ingestion pathways. These processes are:

For toddlers: Incidental ingestion (hand-to-mouth);

Incidental ingestion (turf-to-mouth);

Incidental ingestion (soil-to-mouth);

Incidental dermal;

For adults: Jazzercise (on treated turf).

EPA believes that this screening level assessment will be protective of other possible residential exposures to ethofumesate such as golfing, and mowing the lawn. Exposures were calculated by considering the potential sources of exposure then calculating dermal exposure, and risks.

The Agency calculated Margin of Exposure (MOE)s for each exposure pathway and for all pathway combinations.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ethofumesate and any other substances and ethofumesate 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 ethofumesate 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA 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 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. 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The Agency determined based on the weight-of-the-evidence considerations that there are no concerns or uncertainties for prenatal and/or postnatal toxicity resulting from exposure to ethofumesate. There is evidence for increased quantitative susceptibility following *in utero* exposure to rabbits. At 300 milligrams/kilograms/day (mg/kg/day), no maternal toxicity was reported but developmental toxicity was observed as increased resorptions, post-implantation loss and skeletal abnormalities (incomplete ossification of vertebral arches). No evidence of increased susceptibility was observed in the rat in either the developmental or reproductive toxicity study. In the rat developmental toxicity study, no developmental effects were reported at the highest dose tested (limit dose of 1,000 mg/kg/day). In the 3-generation rat reproductive toxicity study, maternal, reproductive and offspring toxicity were not observed at any dose tested up to 5,000 ppm (396.8 and 462.5 mg/kg/day, males and females, respectively).

The Agency concluded that although increased prenatal quantitative susceptibility was observed in the rabbit developmental toxicity study, there is no concern that the risk assessment will not adequately safeguard against potential prenatal and postnatal toxicity because the developmental toxicity NOAELs/LOAELs are well characterized and are used as endpoints for risk assessment for the appropriate population subgroups.

3. *Conclusion*. The toxicity database for ethofumesate is adequate in terms of endpoint studies and dose response information to characterize any potential prenatal or postnatal risk for infants and children. However, a 28–day inhalation toxicity study has been required to assess inhalation exposure, due to the potential for inhalation exposure during application. In the absence of this study, the inhalation exposure used a 100% default assumption. Additionally, a dermal

absorption (or penetration) study to determine the dermal absorption potential has been required since data on dermal penetration of ethofumesate are unavailable at this time. A default assumption of 100% dermal absorption was selected due to the unavailability of comparative oral and dermal toxicity data with a common endpoint in the same species. There are several uncertainties present in this risk assessment:

i. While ethofumesate toxicological databases are substantially complete, confidence in several areas of the risk assessment would improve with more data. In addition to the requirement for the 28–day inhalation study, data are needed for residue chemistry (i.e, a new cattle feeding study and recovery data for metabolites) as well as for metabolism (i.e. extensive field rotational crop studies).

ii. The extrapolation from oral studies for both the dermal and inhalation portions of the risk assessment in conjunction with a dose spacing concern for the developmental study used to develop residential or occupational assessments for women 13+ years render a highly conservative analysis.

iii. There are uncertainties associated with the drinking water assessment but the limitations related to modeling drinking water exposure did not contribute to an overall concern because the highest aggregate food and water values did not exceed Agency's LOC. Based on the available data, EPA is confident that the values used in this risk assessment are protective. No increase in susceptibility of rats was seen in developmental studies or in a rat 3-generation reproductive study. Although increased prenatal quantitative sensitivity was observed in the rabbit developmental toxicity study, the developmental toxicity NOAELs and LOAELs are well characterized and are used as endpoints for risk assessment for the appropriate population subgroups. The Agency evaluated the potential for increased susceptibility of infants and children from exposure to ethofumesate as required by the FQPA of 1996. All doses for risk assessment purposes were assessed using UFs of 10X for interspecies extrapolation and 10X for intraspecies variability. Acceptable developmental and reproduction studies have been submitted and reviewed.

The Agency evaluated the quality of the exposure data to determine if the the special FQPA (10X) Safety Factor can be reduced based on the following considerations:

Dietary food exposure assessment utilizes proposed tolerance level or higher residues and 100 PCT information for all commodities. By using these screening-level assessments, chronic exposures/risks will not be underestimated.

Dietary drinking water assessment (Tier 1 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

Residential exposure assessment utilizes: Activity specific transfer coefficients and chemical-specific turf transferable residue (TTR) studies for the post-application scenario. The refined residential assessment is based on reliable data and is unlikely to underestimate exposure/risk.

The Agency concluded that there is no concern for prenatal and/or postnatal toxicity resulting from exposure to ethofumesate. Therefore, no special FQPA Safety Factor (i.e. 10X) is needed since there are no residual uncertainties for prenatal and/or postnatal toxicity. Hence, a Safety Factor (1X) was applied.

E. Aggregate Risks and Determination of Safety

In examining aggregate risk, the Agency takes into account all available reliable information concerning exposures from pesticide residues in food and other exposures including drinking water and potential residential exposure to pesticides from such uses as lawn care applications (turf), golf course and others. Aggregate risk assessment considerations must also include potential exposures from oral, dermal and inhalation routes.

1. *Acute risk*. For the acute aggregate risk scenario, food and drinking water exposures were taken into account in the dietary exposure assessment. The estimated dietary exposures (food and water) for females 13–49 years, the only population subgroup of toxicological concern identified at this time, at 4% of the acute Population Adjusted Dose (aPAD). The contribution of food and food forms to this estimate, at the 95th percentile, is 2.1%. A risk estimate that is less than 100% of the aPAD, the dose at which an individual could be exposed on any given day with no adverse health effects, does not exceed the Agency's LOC.

2. *Chronic risk*. For the chronic aggregate risk scenario, food, drinking water, and residential exposures were taken into account. Chronic exposure in residential settings is not expected and the aggregate chronic assessment included food and drinking water only. Since the dietary exposure assessment already includes the highest chronic exposure from the drinking water modeling data, i.e., an estimated maximum 1 in 10 year average concentration of 45.5 ppb no further calculations are necessary. The dietary exposure estimate for all population subgroups was <1% of the chronic Population Adjusted Dose (cPAD) with the most highly exposed subgroup being all infants <1 yrs old. Risk estimates for all population subgroups are below the Agency's LOC (100% of the cPAD).

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

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

For short- and intermediate-term assessments, the oral, dermal and inhalation pathways can be combined due to the common toxicity endpoint via the oral, dermal (oral equivalent) and inhalation (oral equivalent) routes for the appropriate population of concern. For the short-and intermediate-term aggregate risk scenarios, food, drinking water and residential exposures are taken into account. The aggregate short- and intermediate-term MOEs, combining food, drinking water and residential exposures ranged from 160 for all infants <1 yrs old to 270 for the U.S. population. With the exception of women of child-bearing years, residential post-application MOEs for toddlers and adults to ethofumesate on treated turf, regardless of the pathway of exposure, do not exceed the EPA's LOC.

In the case of women of child-bearing years, MOEs are 73 for 1.5 pounds active ingedient/Acre (lb ai/A) application rate for turf and 27 for the 3.0 lb ai/A application rate for turf. The rate of 1.5 lb ai/A covers the majority of uses; however, the label does permit a 3.0 lb ai/A rate specifically for suppression of Bermuda grass in St Augustine grass turf. While the residential postapplication scenarios for females resulted in apparent risks of concern, the Agency believes that these scenarios are very conservative and unlikely to occur. The developmental endpoint used to estimate risk for females was based on a study with a NOAEL (30 mg/kg/day) that is 10X lower than the LOAEL (300 mg/kg/day); therefore the NOAEL may be an artifact of dose selection. Additionally, for the

residential exposures, the endpoint is oral while the assessed exposures are dermal and conservative standard operating procedure (SOP)-based default assumptions such as 100% dermal absorption, default turf transferable residue dissipation assumptions, contact with turf immediately post-treatment and maximum application rates were used in this assessment.

Further, it should be noted that estimated exposures are extremely conservative due not only to assumption of 100% dermal absorption but also because they assume exposure at levels immediately after application, maximal levels of dermal exposure activity, maximum dermal contact, and maximum dermal surface contact areas. Additionally, ethofumesate has minimal lawncare and commercial turf uses, which is the scenario where high dermal exposure activities would occur. The predominant use is on golf courses and sod farms. High exposure activities would likely not occur on a golf course. Ethofumesate residues resulting from sod farm application would likely dissipate significantly before sod was transplanted to residential or commercial turf.

However, to address this concern, the Agency is requiring a dermal absorption study to permit more realistic estimation of dermal absorption. Nonetheless, Agency scientist's consider this a highly conservative estimate of post-application risk for the population females 13-49 years of age exposed to ethofumesate on turf and based on the available data, the EPA is confident that the values used in this risk assessment are protective.

4. *Aggregate cancer risk for U.S. population*. Ethofumesate is classified as ''not likely to be a carcinogen to humans'' based on the lack of carcinogenicity in the mouse carcinogenicity study and lack of convincing evidence for carcinogenicity in the rat chronic toxicity/carcinogenicity study. In addition, no evidence of genotoxicity of ethofumesate was observed in available genotoxicity studies. Therefore, ethofumesate is not expected to pose a cancer risk and a cancer aggregate risk assessment was not performed.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

A tolerance enforcement method is listed as Method I in PAM Vol. II (Section 108.345) for determining the currently regulated residues in plants, which include ethofumesate and its metabolites (free and conjugated). Residues are determined using gas chromatography with flame ionization detector (GC/FID) in the sulfur mode with an internal standard. The reported limit of quantification(LOQ) for each analyte is 0.02 ppm.

Aequate enforcement methodology (gas chromatography with flame ionization detector (GC/FID)) is available to enforce the tolerance expression. The method 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

There is currently no Codex, Canadian, or Mexican maximum residue levels (MRLs) established for ethofumesate, therefore there are no international harmonization issues for this action.

V. Conclusion

Therefore, the tolerance is established for combined residues of ethofumesate, (2-ethoxy -2, 3-dihydro-3, 3-dimethyl-5-benzofuranyl methanesulfonate) and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate (both calculated as the parent compound) in or on the raw agricultural commodities: Carrot, roots (with regional restrictions for us in the States of Washington and Oregon) at 7.0 ppm; beet, garden, tops at 4 ppm; beet, garden, roots at 0.5 ppm; onion, bulb at 0.25 ppm; garlic, bulb at 0.25 ppm; shallot, bulb and shallot, fresh leaves at 0.25 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule

directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

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: August 23, 2006.

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 180.345 is amended as follows:

i. In paragraph (a) by designating the introductory text and table as paragraph (a)(1) and by alphabetically adding commodities to the table; and

ii. Paragraph (c) is amended by adding text and a table.

The amendments read as follows:

§ 180.345 Ethofumesate; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Beet, garden, roots	0.5
Beet, garden, tops	4.0
* * * * *	
Garlic, bulb	0.25
* * * * *	
Onion, bulb	0.25
Shallot, bulb	0.25
Shallot, fresh leaves	0.25
* * * * *	

* * * * *

(c) *Tolerances with regional registration.* Tolerances with regional registration as defined in 40 CFR 180.1(m) are established for the combined residues of ethofumesate,(2-ethoxy -2, 3-dihydro-3, 3-dimethyl-5-benzofuranyl methanesulfonate) and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate (both calculated as the parent compound) in or on the raw agricultural commodities:

Commodity	Parts per million
Carrot, roots	7.0

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[FR Doc. E6–14431 Filed 8–29–06; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–1585; MB Docket No. 05–32; RM–10988]

Radio Broadcasting Services; Homerville, GA and Jacksonville, FL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: At the request of Association for the Studies of American Heritage Corporation, the Audio Division allots Channel 246A at Homerville, Georgia, as that community's second local aural transmission service. To accommodate the Homerville allotment, Station WKQL(FM), Jacksonville, Florida, Channel 245C, is reclassified to specify operation on Channel 245C0. Channel 246A is allotted at Homerville with a site restriction of 11.1 kilometers (6.9 miles) northwest of the community at coordinates 31–07–16 NL and 82–48–51 WL. Station WKQL(FM) is reclassified to specify operation on Channel 245C0 rather than Channel 245C, at Jacksonville, Florida at its license coordinates 30–16–34 NL and 81–33–53 WL. 11.7 kilometers. A filing window period for Channel 246A at Homerville will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent Order.

DATES: Effective September 25, 2006.

ADDRESSES: Secretary, Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 05–32, adopted August 9, 2006, and released August 11, 2006. At the request of Association for the Studies of American Heritage Corporation, the Audio Division allots Channel 246A at Homerville, Georgia, as that community's first local aural transmission service. 70 FR 8333 (February 18, 2005). The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and