metabolites and degradates in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified in the following table are to be determined by measuring only the sum of bifenazate and its metabolite diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate). The tolerances will expire and are revoked on the dates specified in the following table.

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[FR Doc. E9–30138 Filed 12–22–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0536 and 2007–0097; FRL–8793–5]

Fenarimol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenarimol in or on hop, dried cones. This regulation additionally increases the established tolerance in or on apple. Interregional Research Project Number 4 (IR-4) requested the tolerance on hop and EPA proposed the tolerance increase on apple under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 23, 2009. Objections and requests for hearings must be received on or before February 22, 2010, 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–2007–0536. 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 (7505P), 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Test Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/oppts and select ''Test Methods & Guidelines'' on the left side navigation menu*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a(g), 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–2007–0536 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 as required by 40 CFR part 178 on or before February 22, 2010.

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 this copy, identified by docket ID number EPA–HQ–OPP–2007–0536, 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. Petition for Tolerance

In the **Federal Register** of August 22, 2007 (72 FR 47010) (FRL–8142–5) (Docket ID number EPA-HQ-OPP-2007–0536, 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 6E7074) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.421 be amended by establishing tolerances for residues of the fungicide fenarimol,

alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol, in or on hop at 1.0 parts per million (ppm). That notice referenced a summary of the petition prepared on behalf of IR-4 by Gowan Company, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of June 6, 2007 (72 FR 31221) (FRL–8122–7) (Docket ID number EPA-HQ-OPP-2007–0097). EPA issued a proposed rule pursuant to sections 408(e) of FFDCA, 21 U.S.C. 346a(e). The rule proposed that 40 CFR 180.421 be amended by increasing the tolerance for residues of the fungicide fenarimol, alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol, in or on apple from 0.1 ppm to 0.3 ppm. EPA proposed the tolerance increase in order to harmonize with a Codex Maximum Residue Limit (MRL) of 0.3 ppm on apples. The proposal explained the basis for EPA's conclusion that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fenarimol, including exposure under the amended apple tolerance. The proposal established a 60–day public comment period. Comments were received in response to the proposed rule. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance on hop, dried cones. The reason for this change is explained in Unit IV.D.

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 the petitioned-for tolerances for residues of fenarimol on hop, dried cones at 5.0 ppm and apple at 0.3 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Fenarimol has a relatively low order of acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a dermal sensitizer but causes corneal opacity in rabbits. Chronic studies indicated that the liver is a target organ for toxicity. Liver toxicity was manifested by liver weight increases and the presence of ''fatty liver'' in rats. In dogs, increased liver weights and increases in serum enzymes, indicative of liver toxicity, were noted. Additionally, reproduction and developmental studies showed that fenarimol inhibited aromatase, an enzyme involved in the conversion of androgens to estrogens. Two acceptable rodent carcinogenicity studies showed no evidence of significant tumor increases; therefore, fenarimol has been classified as ''not likely to be carcinogenic to humans.'' Additionally, the toxicity database indicates no evidence of mutagenicity or neurotoxicity.

The toxicology data for fenarimol provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies. Developmental kidney effects (hydronephrosis) in the rat were shown to be reversible. The multi-generation reproduction study in rats indicates that fenarimol causes reduced fertility in males and dystocia in females; these effects were attributed to the inhibition of aromatase. Decreased litter size was also noted in the study.

Non-guideline reproductive performance studies in mice, guinea pigs, and rabbits resulted in decreased reproductive performance in male mice, but no such effect in the guinea pig or rabbit studies. A pubertal assay conducted in female rats resulted in decreased T4 thyroid hormone coupled with an increase in circulating thyroid stimulating hormone (TSH) levels. A female rat uterotrophic assay resulted in significant uterine weight increases accompanied by increased serum follicle stimulating hormone (FSH) levels and decreased serum T3 levels.

Specific information on the studies received and the nature of the adverse effects caused by fenarimol 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 ''Fenarimol. Human Health Risk Assessment for the Proposed Food Use of Fenarimol on Hops,'' pages 46 to 49 in docket ID number EPA–HQ–OPP–2007–0536.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 fenarimol used for human risk assessment can be found at *http://www.regulations.gov* in document ''Fenarimol. Human Health Risk Assessment for the Proposed Food Use of Fenarimol on Hops,'' pages 28 to 29 in docket ID number EPA–HQ–OPP–2007–0536.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenarimol, EPA considered exposure under the petitioned-for tolerances as well as all existing fenarimol tolerances in 40 CFR 180.421. EPA assessed dietary exposures from fenarimol 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 fenarimol; 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 United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). The chronic dietary exposure assessment for fenarimol is refined using anticipated residues (ARs) from field trial data, processing factors, and percent crop treated (PCT) data.

ARs based on Food and Drug Administration (FDA) monitoring data were used for apples, bananas, cherries, grapes, and pears. Tolerance values were assumed for foods covered by all additional tolerances. PCT data was used for apples, cherries, grapes, and pears. Dietary Exposure Evalution Model (DEEM) default processing factors were used for all food commodities, except apple juice, pear juice, grape juice, and raisins, which used factors derived from processing studies.

iii. *Cancer*. Based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies, EPA has classified fenarimol as ''not likely to be carcinogenic to humans.'' Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the AR levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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 used PCT information as follows:

Apples, 20%; cherries, 15%; grapes, 25%; and pears, 10%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 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 fenarimol 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 the total residues of concern, including parent fenarimol and its organic degradates (U–1, U–2, U–6, and U–7), in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenarimol. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fenarimol for surface water are estimated to be 66 parts per billion

(ppb) for chronic exposures. For ground water, the estimated drinking water concentration is 19 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 66 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).

Fenarimol is currently registered for use on professionally managed turf areas, such as stadia and golf course tees, greens, and fairways. Short-term postapplication dermal exposure to adult golfers is possible.

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 fenarimol to share a common mechanism of toxicity with any other substances, and fenarimol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenarimol 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 website 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 Food Quality Protection Act (FQPA) safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The database for prenatal developmental (in rats and rabbits) and reproductive (in rats) toxicity is considered complete and includes special studies in addition to conventional guideline studies. The rat developmental study showed evidence of hydronephrosis in fetuses at dose levels equal to or possibly lower than doses causing maternal toxicity; however, a special study showed this effect to be reversible and therefore not considered an adverse effect. Additionally, the decreased live born litter size and survival indices in the rat multi-generation reproduction study are considered to be secondary consequenies of parental effects (e.g. dystocia and fertility), and is not an indicator of increased susceptibility. Therefore, there is no evidence of increased susceptibility of fetuses following *in utero* exposure in the rat or rabbit developmental toxicity study or of offspring following prenatal and postnatal exposure in the rat reproduction study, and there are no concerns or residual uncertainties for prenatal and/or postnatal toxicity.

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 fenarimol is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Harmonized Test Guideline 870.7800) required for pesticide registration; however, the available data for fenarimol do not show potential for immunotoxicity. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional database UF does not need to be applied.

ii. There is no indication that fenarimol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenarimol 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. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilized tolerance-level residues or ARs that are based on reliable field trial data, and factors derived from processing studies (for apple juice, pear juice, grape juice, and raisins) or DEEM default processing factors. For several currently registered commodities, the chronic assessment also utilized PCT data that have a valid basis and are considered to be reliable. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenarimol in drinking water. EPA made similarly conservative assumptions to assess postapplication exposures. These assessments will not underestimate the exposure and risks posed by fenarimol.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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, fenarimol 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 fenarimol from food and water will utilize 76% of the cPAD for infants less than 1–year 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 fenarimol 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). Fenarimol is currently registered for use on professionally managed turf, including stadia and golf

course tees, greens, and fairways, which could result in short-term postapplication dermal exposure to golfers. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fenarimol.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 8,800 for adults 20–49 years old. EPA has determined that this assessment adequately estimates the risk for youth golfers as well. As the aggregate MOE is greater than 1,000 (the LOC), short-term aggregate exposure to fenarimol is not of concern to EPA.

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). Fenarimol is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to fenarimol through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.C.1.iii., EPA has classified fenarimol as ''not likely to be carcinogenic to humans,'' and it 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 fenarimol residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, gas chromatography (GC) with an electrolytic conductivity detector (ECD), is available to enforce the tolerance expression, and is published in the Pesticide Analytical Manual (PAM) Vol. II (Method R039).

B. International Residue Limits

Residue definitions are harmonized between the United States, Codex, and Mexico. In order to harmonize with a Codex MRL of 0.3 ppm for apples, EPA is increasing the tolerance for residues of apples from 0.1 ppm to 0.3 ppm. Additionally, a Codex MRL exists on hop dried cones at 5.0 ppm. The Agency is establishing a tolerance on hop, dried cones at 5.0 ppm to harmonize MRLs between the United States and Codex for this commodity.

C. Response to Comments

EPA received one comment to the proposed rule of June 6, 2007, which made a general objection to the presence of any pesticide residues on crops and stated that EPA should set no pesticide tolerance greater than zero. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances greater than zero may be set when it has been demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the IR-4 petition, EPA revised the proposed tolerance for hop, dried cones from 1.0 ppm to 1.2 ppm. EPA revised the tolerance level 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.'' However, it was discovered that a Codex MRL exists on hops, dried cones at 5.0 ppm. As a result, EPA has increased the hop, dried cones tolerance from 1.2 ppm to 5.0 ppm to harmonize with Codex. The potentially greater exposure under this increased tolerance value was included in EPA's fenarimol risk assessment.

V. Conclusion

Therefore, a tolerance is established for residues of fenarimol, alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol, in or on hop, dried cones at 5.0 ppm. Additionally, the established tolerance of fenarimol in or on apple is increased from 0.1 ppm to 0.3 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) and 408(e) of FFDCA following an agency initiated proposal. 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 on hops, dried cones, 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 to this tolerance. The tolerance on apples, however, was initiated by an EPA proposal and thus the RFA is applicable. Pursuant to the RFA, the Agency hereby certifies that the apple tolerance will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities.

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) (Public Law 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: December 8, 2009.

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. In §180.421 the table in paragraph (a) is amended by revising the entry for ''Apple'' and by alphabetically adding the entry for ''Hop, dried cones'' to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

(a) * * *

Commodity	Parts per million
Apple	0.3
* * * * *	
Hop, dried cones	5.0
* * * * *	

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[FR Doc. E9–30371 Filed 12–22–09; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 240

[Docket No. FRA–2008–0091, Notice No. 4]

RIN 2130–AB95

Qualification and Certification of Locomotive Engineers; Miscellaneous Revisions

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FRA is making miscellaneous amendments to its regulation governing the qualification and certification of locomotive engineers. These changes address the unanticipated consequences arising from reclassifications, clarify the grounds upon which a railroad may revoke a locomotive engineer's certification, and make the regulation consistent with other FRA regulations and guidance. In particular, this rule: prohibits a railroad from reclassifying a person's locomotive engineer certificate to that of a more restrictive class during the period in which the certificate is otherwise valid while permitting the railroad to place restrictions on the locomotive engineer, if appropriate; clarifies that revocation of an engineer's certificate may only occur for the reasons specified in the regulation; requires each railroad to identify the actions it will take in the event that a person fails a skills performance test or the railroad finds deficiencies with an engineer's performance during an operational monitoring observation or unannounced compliance test; requires each railroad to describe the scoring system used by the railroad during performance skills tests, operational monitoring observations and unannounced compliance tests; and makes some minor clarifying revisions to the regulation.

DATES: *Effective Date:* The rule is effective February 22, 2010.

Petitions for reconsideration: Any petition for reconsideration of any portion of the rule must be submitted no later than January 22, 2010.

ADDRESSES: Petitions for reconsideration of this rule should include the agency name and Docket No. FRA–2008–0091, Notice No. 4, and be submitted by any one of the following methods:

- *Fax:* 1–202–493–2251;
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590;
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or
- Electronically through the Federal eRulemaking Portal, *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All petitions for reconsideration received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John L. Conklin, Program Manager, Locomotive Engineer Certification, U.S. Department of Transportation, Federal Railroad Administration, Mail Stop 25, West Building 3rd Floor West, Room W38–208, 1200 New Jersey Avenue, SE., Washington, DC 20590 (*telephone:* 202–493–6318); or John Seguin, Trial Attorney, U.S. Department of Transportation, Federal Railroad