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[FR Doc. E9–25055 Filed 10–15–09; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0076; FRL–8794–4]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the established tolerances for residues of azoxystrobin in or on barley bran; barley grain; and barley straw. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 16, 2009. Objections and requests for hearings must be received on or before December 15, 2009, 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–2009–0076. 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*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2009–0076 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 December 15, 2009.

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–2009–0076, 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 April 8, 2009 (74 FR 15971) (FRL–8407–4), 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 8E7474) by Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.507 be amended by increasing established tolerances for residues of the fungicide azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate], in or on barley, grain from 0.1 parts per million (ppm) to 3.0 ppm and barley, straw from 4.0 ppm to 7.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, Inc., 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.

Based upon review of the data supporting these petitions, EPA has determined that the currently established tolerance in or on barley bran should also be increased and has

determined that the tolerance expression should be revised. 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 the petitioned-for tolerances for residues of azoxystrobin on barley bran at 6.0 ppm; barley grain at 3.0 ppm; and barley straw at 7.0 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.

Azoxystrobin has a low acute toxicity via the oral, dermal and inhalation routes of exposure. It is not an eye or skin irritant and is not a skin sensitizer. Dietary administration of azoxystrobin to rats resulted in decreased body weights, decreased food intake and utilization, increased diarrhea and other clinical toxicity observations (increased urinary incontinence, hunched postures and distended abdomens). In dogs, effects on liver/biliary function were found after oral administration. In the acute neurotoxicity study in rats, increased incidence of diarrhea was observed at all dose levels tested including the lowest-observed-adverse-effect-level (LOAEL). Decreased body weight/weight gain and food utilization was noted in the rat subchronic neurotoxicity study. There were no consistent indications of treatment-related neurotoxicity in either the acute or subchronic neurotoxicity studies.

In the rat developmental toxicity study, diarrhea, urinary incontinence and salivation were observed in maternal animals; in the rabbit developmental toxicity study, maternal animals exhibited decreased body weight gain. No adverse treatment-related developmental effects were seen in either study. In the rat reproduction study, offspring and parental effects (decreased body weights and increased adjusted liver weights) were observed at the same dose.

There was no evidence of carcinogenicity in rats and mice at acceptable dose levels. As a result, EPA has classified azoxystrobin as ''not likely to be carcinogenic to humans.'' Azoxystrobin induced a weak mutagenic response in the mouse lymphoma assay, but the activity expressed *in vitro* is not expected to be expressed in whole animals.

Specific information on the studies received and the nature of the adverse effects caused by azoxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Azoxystrobin. Human Health Risk Assessment for a Section 3 Amendment to Reduce the Preharvest Interval for Barley Grain and Straw and to Add Seed Treatment Uses on Head and Stem *Brassica* Vegetables (Subgroup 5A) and Sorghum, Grain.'', pages 48–51 in docket ID number EPA–HQ–OPP–2009–0076.

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 azoxystrobin used for human risk assessment can be found at *http://www.regulations.gov* in document ''Azoxystrobin. Human Health Risk Assessment for a Section 3 Amendment to Reduce the Preharvest Interval for Barley Grain and Straw and to Add Seed Treatment Uses on Head and Stem *Brassica* Vegetables (Subgroup 5A) and Sorghum, Grain.'', pages 19–20 in docket ID number EPA–HQ–OPP–2009–0076.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to azoxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing azoxystrobin tolerances in 40 CFR 180.507. EPA assessed dietary exposures from azoxystrobin 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues and assumed 100 percent crop treated (PCT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, incorporated PCT data for some existing uses and assumed 100 PCT for the remaining crops including barley.

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

iv. *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 used PCT information as follows:

Almonds, 25%; apricot, 15%; artichoke, 25%; asparagus, 2.5%; blackberries, 5%; blueberries, 10%; broccoli, 5%; cabbage, 5%; cantaloupes, 10%; carrot, 10%; cauliflower, 2.5%; celery, 10%; cherry, 5%; cottonseed, 5%; cucumber, 15%; dried beans/peas, 1%; field corn, 2.5%; filbert (hazelnut), 5%; garlic, 60%; grape, 5%; grapefruit, 25%; green beans, 5% lettuce, 2.5%; mustard greens, 15%; onion, 10%; orange, 5%; green peas, 2.5%; peach, 5%; peanut, 15%; pecan, 2.5%; pepper, 15%; pistachio, 20%; potato, 30%; pumpkin, 20%; raspberry, 5%; rice, 35%; soybean, 2.5%; spinach, 10%; squash, 15%; strawberry, 30%; sugar beets, 5%; sweet corn, 10%; tangerine, 20%; tomato, 15%; walnut, 1%; watermelon, 20%; and wheat, 2.5%.

In most cases, EPA uses available data from 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 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 azoxystrobin 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 azoxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of azoxystrobin. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of azoxystrobin for surface water are estimated to be 173 parts per billion (ppb) for acute exposures and 33 ppb for chronic exposures. For ground water, the estimated drinking water concentration is 3.1 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 173 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 33 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).

Azoxystrobin is currently registered for the following uses that could result in residential exposures: Turf grass, ornamentals, indoor surfaces, and treated paints (preservative incorporation). EPA assessed residential exposure using the following assumptions: Adults were assessed for short-term inhalation exposures when mixing, loading and applying azoxystrobin. For short-term and intermediate-term postapplication exposures, toddlers and children were assessed for incidental oral exposure (hand-to-mouth exposure, object-to-mouth exposure and exposure through incidental ingestion of soil) from contact with treated foliage and surfaces. Adults were not assessed for intermediate-term risk, as intermediate-term residential handler scenarios are not expected to occur. A dermal exposure assessment was not conducted for residential handlers or for postapplication activities because no dermal endpoint was identified.

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 azoxystrobin to share a common mechanism of toxicity with any other substances, and azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that azoxystrobin 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 FQPA 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*. The prenatal and postnatal toxicity database for azoxystrobin is complete and includes prenatal developmental toxicity studies in rats and rabbits and a 2–generation reproduction study in rats. In these studies, offspring toxicity was observed at equivalent or higher doses than those resulting in parental toxicity; thus, there is no evidence of increased susceptibility and there are no residual uncertainties with regard to prenatal and/or postnatal toxicity.

3. *Conclusion*. EPA has reduced the FQPA SF to 3X in assessing acute dietary risk. An additional safety factor is needed for acute risk assessment to account for the use of a LOAEL from the acute neurotoxicity study in rats in deriving the acute reference dose used for assessing acute dietary exposure for all populations including infants and children. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. To account for the use of a LOAEL from the acute neurotoxicity study in rats the Agency believes that a 3X FQPA SF (as opposed to a 10X) will be adequate to extrapolate a NOAEL in assessing acute risk and that no additional safety factor is needed for short-term, intermediate-term, and chronic risk assessment based on the following considerations:

i. The concern is low for the use of a LOAEL to extrapolate a NOAEL, given the relatively insignificant nature of the effect (transient diarrhea seen in the rat); the fact that diarrhea was only seen in studies involving gavage dosing in the rat but not in repeat dosing through dietary administration in rats, mice, rabbits, and dogs; the very high dose level needed to reach the acute oral lethal dose $(LD)_{50}$ (>5000 milligrams/kilogram (mg/kg)), and the overall low toxicity of azoxystrobin. NOAELs were used for short-term, intermediate-term, and chronic risk assessments.

ii. The toxicity database for azoxystrobin is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required 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. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by azoxystrobin and azoxystrobin does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations in this unit, EPA does not believe that conducting the immunotoxicity study will result in a dose less than the point of departure already used in this risk assessment, and an additional database uncertainty factor for potential immunotoxicity does not need to be applied.

iii. Clinical signs noted in the acute and subchronic neurotoxicity studies were not considered treatment related because of a lack of dose-response, inconsistency of observations at different time points, variability of pretreatment values and/or small magnitude of response. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. There is no evidence that azoxystrobin results in increased susceptibility to *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

v. The acute and chronic dietary exposure assessments were performed based on tolerance-level residues. The acute dietary assessment incorporated 100 PCT information, and the chronic dietary exposure assessment was somewhat refined using PCT information for selected crops. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to azoxystrobin 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 azoxystrobin.

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. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 70% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to azoxystrobin from food and water will utilize 9.6% 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 azoxystrobin is not expected.

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

is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to azoxystrobin.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 240 for children 1–2 years old (the population group receiving the greatest exposure), and has concluded the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 340 for children 1–2 years old (the population group receiving the greatest intermediate-term exposure). As the aggregate MOEs for short-term and intermediate-term exposure are greater than 100 (the LOC) for all population subgroups assessed, short-term and intermediate-term aggregate exposures to azoxystrobin are not of concern to EPA.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in mice and rats in two adequate carcinogenicity studies, azoxystrobin was classified as ''not likely to be carcinogenic to humans,'' and is not expected to pose a cancer risk to humans.

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, or to infants and children from aggregate exposure to azoxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression and have been submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM) Volume II: A gas chromatography method with nitrogen-phosphorus detection (GC/NPD), RAM 243/04, for the enforcement of tolerances for residues of azoxystrobin and its Z-isomer in crop commodities; and a GC/NPD method, RAM 255/01, for the enforcement of tolerances of azoxystrobin in livestock commodities. 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

Codex Maximum Residue Limits (MRLs) have been established for azoxystrobin in or on barley grain at 0.5 ppm; and straw and fodder of cereal grains (except maize) at 15 ppm. The Codex MRLs for barley grain and straw are based on field trials conducted in Europe and on residues present at a 35–42 day pre-harvest interval (PHI). The recommended U.S. tolerances on barley grain (3.0 ppm) and straw (7.0 ppm) are based on residues present at a 14–day PHI. The U.S. tolerance for barley grain is higher due to the shorter PHI; thus, the barley grain tolerance and MRLs cannot be harmonized between the U.S. and Codex. Codex MRLs for forages, straws and the like are set on a dry-weight basis, whereas U.S. tolerances are set on an as-fed basis; therefore, the U.S. tolerance on barley straw cannot be harmonized with the Codex MRL for straw and fodder of cereal grains (including barley, oats, rice and wheat data) at this time.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has revised the existing tolerance for barley bran from 0.2 ppm to 6.0 ppm. Based on previously-submitted wheat processing data, a tolerance for barley bran was established at 0.2 ppm; however, the proposed PHI reduction for barley grain results in higher residues in barley grain and the potential for increased residues in barley bran. Using the highest average field trial data for barley grain harvested at the 14–day PHI (1.85 ppm) and the concentration factor for wheat bran (3x), expected residues in barley bran would be 5.55 ppm. The expected barley bran residues exceed the proposed tolerance increase for barley grain at 3.0 ppm and the existing tolerance for barley bran at 0.2 ppm. Therefore, the Agency is increasing the established tolerance for azoxystrobin in or on barley bran from 0.2 ppm to 6.0 ppm.

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 azoxystrobin 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. This change was made to both the tolerance expressions for plant commodities and animal commodities because it makes no substantive change to the meaning of the tolerance but rather only clarifies the existing language.

V. Conclusion

Therefore, established tolerances are amended for residues of azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate], in or on barley, bran at 6.0 ppm; barley, grain at 3.0 ppm; and barley, straw at 7.0 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) (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: October 7, 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. Section 180.507 is amended in paragraph (a)(1) by revising the introductory text and by revising the entries for ''Barley, bran''; ''Barley, grain''; and ''Barley, straw'' in the table; and in paragraph (a)(2) by revising the introductory text to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide, azoxystrobin, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], and the Z-isomer of azoxystrobin [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate] in or on the commodity.

Commodity	Parts per million
* * * * *	
Barley, bran	6.0
* * * * *	
Barley, grain	3.0
* * * * *	
Barley, straw	7.0
* * * * *	

(2) Tolerances are established for residues of the fungicide, azoxystrobin, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], and the Z-isomer of azoxystrobin [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate] in or on the commodity.

* * * * *

[FR Doc. E9–24813 Filed 10–15–09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2008–0020; Internal Agency Docket No. FEMA–8099]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register.**

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The