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■ 3. In § 52.1072, paragraph (d) is removed and reserved.

■ 4. In § 52.1073, paragraph (e) is removed and reserved.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0270; FRL–8413–7]

Acibenzolar-S-methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acibenzolar-S-methyl in or on onion, bulb, subgroup 3-07A; and vegetable, cucurbit, group 9. It also removes the section 18 time-limited tolerance on onion, bulb which is superseded by the new tolerance on onion, bulb, subgroup 3-07A. Interregional Research Project Number 4 (IR-4) and Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 26, 2009. Objections and requests for hearings must be received on or before July 27, 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–2008–0270. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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–2008–0270 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 July 27, 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–2008–0270, 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 May 16, 2008 (73FR 28461) (FRL–8361–6), 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 8E7337) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.561 be amended by establishing a tolerance for residues of the fungicide acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, in or on onion, bulb, subgroup 3-07A at 0.07 parts per million (ppm). That notice referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, 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 December 3, 2008 (73 FR 73644) (FRL–8386–9), 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 8F7352) by Syngenta Crop Protection, Regulatory Affairs, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.561 be amended by establishing a tolerance for residues of the fungicide acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, in or on vegetable, cucurbit, group 9 at 1.0 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available to the public in docket ID number EPA–HQ–OPP–2008–0733 at *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has revised the tolerance expression and increased the tolerance level for onion, bulb, subgroup 3-07A from 0.07 ppm to 0.1 ppm; and for vegetable, cucurbit, group 9 from 1.0 ppm to 2.0 ppm. 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 acibenzolar-S-methyl on onion, bulb, subgroup 3-07A at 0.1 ppm; and vegetable, cucurbit, group 9 at 2.0 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.

Acibenzolar-S-methyl showed no significant toxicity in a battery of acute toxicity tests but showed considerable skin-sensitivity. In subchronic and chronic oral studies in rats, dogs and mice, signs of mild regenerative hemolytic anemia were consistently observed in all three species. Additional toxic effects observed in these studies included decreases in body weight, body weight gain and/or food consumption. No other significant treatment-related effects of toxicological concern were observed in these subchronic and chronic oral studies. No neurotoxic effects were seen at the highest dose tested in a subchronic neurotoxicity study in rats. In a 28–day dermal toxicity study in rats no systemic or dermal effects were seen at the limit dose.

In developmental toxicity and developmental neurotoxicity (DNT) studies in rats, treatment-related effects (visceral malformations and skeletal variations; changes in brain morphometrics in the cerebellum) were observed in fetuses at levels that were not toxic to the parent, indicating increased sensitivity of rat fetuses compared to adults. Increased sensitivity was not observed in a developmental toxicity study in rabbits, or in 1-generation and 2-generation reproduction studies in rats. In a 28–day dermal developmental toxicity study in rats, no maternal or developmental toxicity was observed at dose levels up to 500 mg/kg/day, the highest dose level tested.

Acibenzolar-S-methyl was classified by EPA as a ''not likely'' human carcinogen based on the lack of evidence of carcinogenicity in male and female rats and mice and lack of evidence of genotoxicity in an acceptable battery of mutagenicity studies.

Specific information on the studies received and the nature of the adverse effects caused by acibenzolar-S-methyl 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 the document *Revised Acibenzolar-S-methyl Human Health Risk Assessment for Proposed Use of Acibenzolar-S-methyl on Cucurbits and Bulb Onions* page 34 in docket ID number EPA–HQ–OPP–2008–0270.

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 acibenzolar-S-methyl used for human risk assessment can be found at *http://www.regulations.gov* in the document *Revised Acibenzolar-S-*

methyl Human Health Risk Assessment for Proposed Use of Acibenzolar-S-methyl on Cucurbits and Bulb Onions page 21 in docket ID number EPA–HQ–OPP–2008–0270.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acibenzolar-S-methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing acibenzolar-S-methyl tolerances in 40 CFR 180.561. EPA assessed dietary exposures from acibenzolar-S-methyl 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. EPA identified such an effect (changes in brain morphometrics in the cerebellum of offspring) in the developmental neurotoxicity study in rats. This acute endpoint is relevant to the population subgroup, females 13 to 49 years old. No acute endpoint of concern was identified for the general population or other population subgroups.

In estimating acute dietary exposure of females 13 to 49 years old, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). EPA conducted a partially refined, probabilistic acute dietary exposure assessment using the distribution of residues from field trial data for each food commodity. The probabilistic assessment incorporated empirical processing factors for some processed commodities (tomato paste, puree and juice) and DEEM™ default processing factors for the remaining processed commodities. Exposure estimates were further refined using maximum percent crop treated (PCT) information for most existing uses of acibenzolar-S-methyl. EPA assumed 100 PCT for the new uses on onions and cucurbits.

The acibenzolar residues of concern for risk assessment include acibenzolar-S-methyl, benzo(1,2,3) thiadiazole-7-carbothioic acid-S-methyl ester, convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as acibenzolar-S-methyl; and its 4-hydroxy CGA-210007 (CGA-323060) and 5-hydroxy CGA-210007 (CGA-324041) metabolites. A factor of 1.5x, based on the relative abundance of the hydroxy metabolites (CGA-323060 and CGA-324041) and residues convertible to the carboxylic acid metabolite (CGA-210007) found in the lettuce metabolism study, was applied to estimates of acibenzolar-S-methyl residues to account for all of the residues of concern for dietary risk (including CGA-210007, CGA-323060 and CGA-324041).

ii. *Chronic exposure.* EPA identified different chronic effects of concern for the general population (hemolytic anemia with compensatory response observed in the chronic dog study) and for females 13 to 49 years old (changes in brain morphometrics in the cerebellum of offspring in the DNT study). The cPAD for the general population has been established at 0.25 mg/kg/day; whereas, the cPAD for females 13 to 49 years old is lower (0.082 mg/kg/day), due to the more sensitive endpoint on which it is based. 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 assumed tolerance-level residues (adjusted by a factor of 1.5x to account for all metabolites of concern), DEEM™ default processing factors and 100 PCT for all commodities.

iii. *Cancer.* Based on the lack of evidence of carcinogenicity in male and female rats and mice and lack of evidence of genotoxicity in an acceptable battery of mutagenicity studies, EPA classified acibenzolar-S-methyl as a ''not likely'' human carcinogen. Therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue 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:

Broccoli 5%, cabbage 2.5%, cauliflower 5%, celery 1%, lettuce (head and leaf) 12%, pepper (bell and non-bell) 5%, spinach 30%, and tomato 5%.

In most cases, EPA uses available data from United States Department of Agriculture/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 acibenzolar-S-methyl may be applied in a particular area.

2. *Dietary exposure from drinking water*. The residues of concern for drinking water include acibenzolar-S-methyl and residues convertible to CGA-210007. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acibenzolar-S-methyl and CGA-210007 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acibenzolar-S-methyl. 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 acibenzolar-S-methyl and CGA-210007 for acute exposures are estimated to be 0.74 and 14.21 parts per billion (ppb), respectively, for surface water and 0.000041 and 0.557 ppb, respectively, for ground water. EDWCs of acibenzolar-S-methyl and CGA-210007 for chronic exposures for non-cancer assessments are estimated to be 0.10 and 9.48 ppb, respectively, for surface water and 0.000041 and 0.557 ppb, respectively, for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. CGA-210007 drinking water residues were included in the dietary exposure assessment as acibenzolar-S-methyl equivalents. CGA 210007 residues were converted to acibenzolar-S-methyl equivalents based on molecular weight (mol. wt. of acibenzolar (210) ÷ mol. wt. of CGA 210007 (180) x EDWC for CGA 210007). For acute dietary risk assessment, the water concentration value of 17 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 11 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). Acibenzolar-S-methyl is not registered for any specific use patterns that would result in residential exposure.

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

In previous risk assessments for acibenzolar-S-methyl the 10X FQPA safety factor was retained for increased quantitative susceptibility (umbilical hernia) observed in a rat developmental toxicity study and the lack of a developmental-neurotoxicity (DNT) study. A DNT study has now been submitted and reviewed by EPA; and, based on reevaluation of existing data and review of newly submitted data, the umbilical hernias are no longer considered to be treatment-related. EPA concluded that the incidence of umbilical hernias at 10 milligram/kilogram/day (mg/kg/day) was not a treatment-related adverse effect because the effect is not dose-related (i.e., it was seen only at the low dose of 10 mg/kg/day); the effect was not seen in dosed animals in other studies, including developmental toxicity studies and reproduction studies; umbilical hernia was observed in the control animals in the rat dermal developmental toxicity study (1/336 fetuses in 1 of 24 litters); and the effect is known to occur spontaneously in the rat strain used in this study. New studies, including a DNT study in rats, a developmental toxicity study in rats and two non-standard investigative, phase-specific studies, support the finding that incidence of umbilical hernias is not treatment-related. Based on these findings, EPA has reconsidered the FQPA safety factor for acibenzolar-S-methyl.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicity database for acibenzolar-S-methyl includes acceptable developmental toxicity studies in rats (two oral and one dermal) and rabbits (one oral); a DNT study in the rat; and 1-generation and 2-generation reproduction toxicity studies in the rat.

There was no evidence of increased susceptibility of fetuses or offspring in the rat dermal developmental toxicity study, the rabbit developmental toxicity study or the rat reproduction toxicity studies. No maternal or fetal effects were observed in the dermal developmental study at any dose tested. In the rabbit developmental study, maternal effects (mortality, clinical signs, decreased maternal body weight and food consumption) were seen at a lower dose than fetal effects (marginal increase in vertebral anomalies). In the rat reproduction studies, parental effects (increased weights and hemosiderosis of the spleen; decreased body weight gain and food consumption in females) and offspring effects (reduced pup body weight gains and lower pup body weights during lactation) were seen at the same dose.

In the developmental toxicity and DNT studies in rats, treatment-related effects (visceral malformations and skeletal variations; and changes in brain morphometrics in the cerebellum) were observed in offspring at levels that were not toxic to the parent, indicating potential increased quantitative susceptibility of offspring compared to adults. The developmental no-observed

adversed-effect level (NOAEL) from the DNT study (8.2 mg/kg/day) is the lowest NOAEL from any study in the acibenzolar database and is the POD used in both the acute and chronic dietary exposure assessments for females, 13 to 49 years old, the relevant population subgroup for assessing potential developmental effects. Since there is a well-defined NOAEL for these effects and the NOAEL is being used as the POD in the risk assessment, there are no residual uncertainties with regard to pre- or postnatal sensitivity.

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 acibenzolar-S-methyl is complete, except for immunotoxicity studies, and EPA has determined that an additional uncertainty factor is not required to account for potential immunotoxicity. The reasons for this determination are explained below:

EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement is relatively new, these studies are not yet available for acibenzolar-S-methyl. In the absence of specific immunotoxicity studies, EPA has evaluated the available acibenzolar-S-methyl toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by acibenzolar-S-methyl. While effects on the spleen were observed in association with hematologic effects, these were considered to be secondary to the primary effects on blood hematology. Effects on the thymus were seen in only one study in one animal at a high dose (400 mg/kg/day) and were, therefore, considered to be spurious. Due to the lack of evidence of immunotoxicity for acibenzolar-S-methyl, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the chronic NOAELs of 8.2 mg/kg/day (females, 13 to 49 years old) or 25 mg/kg/day (all other populations) already established for acibenzolar-S-methyl, and an additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity.

ii. There was no evidence of neurotoxicity in the subchronic neurotoxicity study submitted for acibenzolar-S-methyl. Based on the results of this study, EPA has determined that an acute neurotoxicity study is not required. There was evidence of offspring neurotoxicity (changes in brain morphometrics in the cerebellum) in the rat DNT study in the absence of maternal toxicity; however, since the NOAEL for these effects is being used in the acute and chronic risk assessments for females, 13 to 49 years old, there are no residual uncertainties with regard to these effects and no need for additional UFs to account for neurotoxicity.

iii. Although there was evidence of increased quantitative susceptibility of offspring to acibenzolar-S-methyl in the rat developmental toxicity and DNT studies, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using tolerance levels or anticipated residues derived from reliable field trials and screening-level PCT estimates. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to acibenzolar-S-methyl in drinking water. Residential exposure to acibenzolar-S-methyl is not expected. These assessments will not underestimate the exposure and risks posed by acibenzolar-S-methyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (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 acibenzolar-S-methyl will occupy 12% of the aPAD for females, 13 to 49 years old, the only population group for which an acute endpoint of toxicological concern was identified.

2. *Chronic risk*. EPA performed two different chronic risk assessments – one focusing on females 13 to 49 years old and designed to protect against neurotoxic effects in offspring and the other focusing on chronic effects (hemolytic anemia) relevant to all other population groups. The more sensitive chronic endpoint was seen as to offspring effects rather than other chronic effects. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that for females, 13 to 49 years old, chronic exposure to acibenzolar-S-methyl from food and water will utilize 5% of the cPAD addressing offspring effects. As to other chronic effects, chronic exposure to acibenzolar-S-methyl from food and water will utilize 4% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for acibenzolar-S-methyl.

3. *Short-term intermediate-term risk*. Short-term and intermediate-term aggregate exposures take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acibenzolar-S-methyl is not registered for any use patterns that would result in residential exposure. Therefore, the short-term and intermediate-term aggregate risk is the sum of the risk from exposure to acibenzolar-S-methyl through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Acibenzolar is classified as a ''not likely'' human carcinogen and is, therefore, not expected to pose a cancer risk.

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 acibenzolar-S-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography with Ultraviolet Detection (HPLC/UV) Method AG-671A) 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

No Codex, Mexican or Canadian maximum residue limits have been established for acibenzolar-S-methyl on any commodity.

C. Revisions to Petitioned-For Tolerances

The petitioners proposed tolerances for residues of ''acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester.'' Since the analytical method for acibenzolar is a common-moiety method that converts all residues containing the benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007) moiety to CGA-210007, EPA has revised the tolerance expression to read ''acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, including its metabolites and degradates.

EPA has also increased the tolerance level for onion, bulb, subgroup 3-07A from 0.07 ppm to 0.1 ppm; and for vegetable, cucurbit, group 9 from 1.0 ppm to 2.0 ppm. The residue data submitted for onions and previously submitted data for tobacco suggest that drying may tend to concentrate residues of acibenzolar-S-methyl. To ensure that the tolerance level is adequate, EPA has increased the tolerance for onion, bulb, subgroup 3-07A from 0.07 to 0.1 ppm. EPA increased the tolerance for cucurbits from 1.0 to 2.0 ppm based on the indication of variability within and between the cucurbit vegetable data sets (cantaloupe, cucumber and summer squash), as well as the demonstrated potential for significant increases in acibenzolar-S-methyl residues 0 to 7 days before harvest.

V. Conclusion

Therefore, tolerances are established for residues of acibenzolar-S-methyl benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, including its metabolites and degradates, in or on onion, bulb, subgroup 3-07A at 0.1 ppm; and vegetable, cucurbit, group 9 at 2.0 ppm. Compliance with the specified tolerance levels is to be determined by measuring only those acibenzolar-S-methyl residues convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as the stoichiometric equivalent of acibenzolar-S-methyl, in or on the commodity.

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: May 15, 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 180.561 is amended by revising paragraph (a) and paragraph (b) in the table by removing the entry for onion, bulb to read as follows:

§ 180.561 Acibenzolar-S-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, in or on the following raw agricultural commodities:

Commodity	Parts per million
Banana[1]	0.1
Spinach	1.0
Tomato, paste	3.0
Vegetable, brassica, leafy, group 5	1.0
Vegetable, fruiting, group 8	1.0
Vegetable, leafy, group 4	0.25

[1]There are no United States registrations for banana.

(2) Tolerances are established for residues of acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only those acibenzolar-S-methyl residues convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as the stoichiometric equivalent of acibenzolar-S-methyl, in or on the commodity.

Commodity	Parts per million
Onion, bulb, subgroup 3–07A	0.1
Vegetable, cucurbit, group 9	2.0

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