ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0214; FRL–7697–8]

Acibenzolar-*S*-methyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of acibenzolar-*S*-methyl in or on onion, dry bulb and onion, green. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on onion, dry bulb and onion, green. This regulation establishes a maximum permissible level for residues of acibenzolar-*S*-methyl in these food commodities. These tolerances will expire and are revoked on June 30, 2007.

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0214. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall # 2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, EnvironmentalProtection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:703 308–9364; e-mail address:*pemberton.libby@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, in or on onion, dry bulb and onion, green at 0.05 parts per million (ppm). These tolerances will expire and are revoked on June 30, 2007. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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....''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Acibenzolar-*S*-methyl on Bulb Onions and Green Onions and FFDCA Tolerances

Iris yellow spot virus is a new and expanding pest problem. Onion thrips transmit the virus which cause leaf and flower stalk lesions, as well as smaller sized bulbs. Production seed can also be infected. Economic consequences can be significant due to yield losses. The virus also reduces bulb size causing reduction in grade. EPA has authorized under

FIFRA section 18 the use of acibenzolar-*S*-methyl on onion, dry bulb and onion, green, for control of iris yellow spot virus in Colorado. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of acibenzolar-*S*-methyl in or on onion, dry bulb and onion, green. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on June 30, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on onion, dry bulb and onion, green after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether acibenzolar-*S*-methyl meets EPA's registration requirements for use on onion, dry bulb and onion, green or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of acibenzolar-*S*-methyl by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Colorado to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for acibenzolar-*S*-methyl, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the 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 acibenzolar-*S*-methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for residues of acibenzolar-*S*-methyl in or on onion, dry bulb and onion, green at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

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. The toxicology database for acibenzolar-*S*-methyl is incomplete. Subchronic neurotoxicity, developmental neurotoxicity and an additional mutagenicity study (Ames study) are required. EPA has considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by acibenzolar-*S*- methyl are fully discussed in a final rule published in the **Federal Register** on August 18, 2000 (65 FR 50438)(FRL–6737–6) that established tolerances for residues of acibenzolar-*S*-methyl in or on bananas, Brassica (cole) leafy vegetables, fruiting vegetables, leafy vegetables and spinach. Please refer to that document for a complete discussion of the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. No NOAEL for developmental toxicity was observed in the rat developmental study for acibenzolar-*S*-methyl. Because no NOAEL was observed, an additional 3X uncertainty factor is being applied to the 100X uncertainty factor to account for intra- and inter-species variability, resulting in a 300X UF for toxicological endpoints derived from this study.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point

of departure/exposures) is calculated. A summary of the toxicological endpoints for acibenzolar-*S*-methyl used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ACIBENZOLAR-*S*-METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 10 milligrams/kilogram/day (mg/kg/day). UF = 300 Acute RfD = 0.033 mg/kg/day	FQPA SF = 10 ..... aPAD = acute RfD ÷ FQPA SF = .0033 mg/kg/day	Developmental toxicity LOAEL = 10 mg/kg/day based on increased incidence of rare malformations (umbilical hernias).
Acute Dietary (General population including infants and children)	None	None	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on acibenzolar-*S*-methyl that would be applicable to the general population (including infants and children).
Chronic Dietary (Females 13–50 years of age)	NOAEL= 10 mg/kg/day ..... UF = 300 Chronic RfD = .033 mg/kg/day	FQPA SF = 10 ..... cPAD = chronic RfD ÷ FQPA SF = .0033 mg/kg/day	Developmental toxicity LOAEL = 10 mg/kg/day based on increased incidence of rare malformations (umbilical hernias).
Chronic Dietary (All other populations, including infants and children)	NOAEL= 10.8 mg/kg/day ..... UF = 100 Chronic RfD = 0.11 mg/kg/day	FQPA SF = 3 ..... cPAD = chronic RfD ÷ FQPA SF = 0.0367 mg/kg/day	Carcinogenicity study - mice; LOAEL (Females) = 234 mg/kg/day based on mild hemolytic anemia and hemosiderosis of the liver, spleen, and bone marrow, and extramedullary hematopoiesis of the spleen.
Cancer (oral, dermal, inhalation)	None	None	Acibenzolar-*S*-methyl has been classified as a ''not likely'' human carcinogen. This classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of unequivocal genotoxicity in an acceptable battery of mutagenicity studies performed on the current technical grade product.

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.561) for the residues of acibenzolar-*S*-methyl, in or on a variety of raw agricultural commodities including bananas, Brassica (cole) leafy vegetables, fruiting vegetables, leafy vegetables, spinach and tomato paste. Risk assessments were conducted by EPA to assess dietary exposures from acibenzolar-*S*-methyl in food as follows:

i. *Acute exposure.* Acute dietary 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 one day or single exposure. Probabilistic (i.e., Monte Carlo) acute dietary risk assessments were conducted for acibenzolar-*S*-methyl using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994–1996 and 1998 and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: For onions, the recommended tolerance level of 0.05 ppm was used and the assumption of 100% crop treated was made. DEEM default processing factors were used for dried onion, dried banana, dried plantain, and dried tomato. Empirical processing factors were used for tomato paste (7.1), tomato puree (2.9), and tomato juice (1.0). Blended commodities were treated differently than nonblended and partially blended commodities. Foods were classified as blended, partially blended, or nonblended. For blended commodities, the mean field trial values were used as a point estimate for expected residues. A value of ½ the limit of quantitation(LOQ) was used for samples that contained less than LOQ residues. Maximum percent crop treated (PCT) estimates were used as residue adjustment factors. The blended commodities included dried bananas, dried plantains, dried bell peppers, dried nonbell peppers, dried tomatoes, tomato paste, and tomato puree. For nonblended and partially blended commodities, the distributions of the field trial data were used. Again, a value

of ½ LOQ was used for samples that contained less than LOQ residues. Maximum PCT estimates were used for brocolli, cabbage, cauliflower, celery, head lettuce, leaf lettuce, spinach, peppers, and tomatoes.

ii. *Chronic exposure*.In conducting this chronic dietary risk assessment the DEEM-FCID, Version 2.03, which uses food consumption data from the USDA's CSFII from 1994–1996 and 1998 and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: tolerance level residues for all crops and 100% crop treated were used.

iii. *Cancer*. Acibenzolar-*S*-methyl has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative exposure assessment was not conducted to assess cancer risk.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that 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 such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

In assessing chronic risk, EPA did not use PCT data. In assessing acute risk, The Agency used PCT information as follows: for onions the assumption of 100% crop treated was made. The following maximum PCT estimates were used: 1% of broccoli, 1% of cabbage, 1% of cauliflower, 1% celery, 12% head lettuce, 12% leaf lettuce, 1% peppers, 15% spinach and 1% tomatoes. For all other commodities it was assumed 100% of the crop was treated.

EPA believes that the PCT information described above for acibenzolar-*S*-methyl on leafy vegetables, fruiting vegetables and brassica (cole) leafy vegetables is reliable and has a valid basis. The PCT information is based on reliable estimates of the potential market for acibenzolar-*S*-methyl and the petitioner's estimate of the market share it expects to capture. EPA believes the estimates do not underestimate the percent of these crops that may be treated.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for acibenzolar-*S*-methyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of acibenzolar-*S*-methyl.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW (screening concentration in ground water), which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to acibenzolar-*S*-methyl they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of acibenzolar-*S*-methyl for acute exposures are estimated to be 7.9 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.49 ppb for surface water and 0.02 ppb for ground 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 use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to acibenzolar-*S*-methyl and any other substances and acibenzolar-*S*-methyl does not appear to produce a toxic

metabolite produced by other substances. EPA has also evaluated comments submitted that suggested there might be a common mechanism among acibenzolar-*S*-methyl and other named pesticides that cause brain effects. EPA concluded that the evidence did not support a finding of common mechanism for acibenzolar-*S*-methyl and the named pesticides. For the purposes of this tolerance action, therefore, EPA has not assumed that acibenzolar-*S*-methyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA's risk assessments either directly through use of a margin of exposure (MOE) analysis or through using UFs (safety) in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies*. In a prenatal developmental study in rats the maternal NOAEL is 200 mg/kg/day and the LOAEL is 400 mg/kg/day based on hemorrhagic perineal discharge. A developmental NOAEL was not identified. The LOAEL is 10 mg/kg/day (lowest dose tested) based on umbilical hernia.

In a prenatal developmental study in rabbits the maternal NOAEL is 50 mg/kg/day and the LOAEL is 300 mg/kg/day based on mortality, clinical signs of toxicity, decreased maternal body weight and food consumption. The developmental NOAEL is 300 mg/kg/day and the LOAEL is 600 mg/kg/day based on a marginal increase in vertebral anomalies.

3. *Reproductive toxicity study*. In a reproduction and fertility study, the parental/systemic NOAEL is 11 to 31 mg/kg/day and the LOAEL is 105 to 288 mg/kg/day based on increased weights and hemosiderosis of the spleen. The reproductive NOAEL is 223 to 604 mg/kg/day and the LOAEL is greater than 223 to 604 mg/kg/day based on no effects. The offspring NOAEL is 11 to 31 mg/kg/day and the LOAEL is 105 to 288 mg/kg/day based on reduced pup body weight gains and lower pup body weights during lactation.

4. *Prenatal and postnatal sensitivity*. The Agency concluded that there is concern for the increased susceptibility of infants and children to exposure to acibenzolar-*S*-methyl based on the developmental toxicity study in rats where treatment-related developmental malformations, anomalies and variations were observed at doses equal to or below the NOAEL for maternal toxicity.

5. *Conclusion*. The toxicology database for acibenzolar-*S*-methyl is incomplete. Subchronic neurotoxicity, developmental neurotoxicity and an additional mutagenicity study (Ames study) are required. When assessing acute and chronic dietary exposures, the Agency concluded that the FQPA safety factor should be retained at 10X for the female, 13 to 50 years old, population subgroup (the only population subgroup of concern for acute exposures). The Agency recognizes that the fetal effects occurring in the rat developmental study are of significant toxicological concern and that a developmental neurotoxicity study has been required to further define the neurotoxic potential observed in this study. However, the Agency concluded that a safety factor of 10X is adequate in this case since:

i. The Agency has accounted for the concern that these fetal effects occurred at the lowest dose tested (no developmental NOAEL established) by the requirement of an additional uncertainty factor of 3X when this endpoint is used for risk assessment.

ii. These fetal effects were only observed in one species (in the rat but not in the rabbit).

iii. These fetal effects were not observed in the 2-generation reproduction study.

iv. The exposure databases are well characterized and the exposure assessments will not likely underestimate the exposure resulting from the use of acibenzolar-*S*-methyl. Therefore, the Agency concluded that the FQPA Safety Factor be retained at 10X for females, 13 to 50 years old based on:

a. A quantitative increase in susceptibility of fetuses (compared to dams) in the rat developmental toxicity study (developmental malformations occurred at a dose level which was considerably below the NOAEL for maternal toxicity).

b. A concern that the treatment-related developmental malformations (umbilical hernia) observed in rat fetuses occurred at the lowest dose tested (NOAEL was not established) in the rat developmental toxicity study.

c. The requirement for a developmental neurotoxicity study in rats based on the occurrence of treatment-related effects in nervous system tissues in the rat developmental study.

The data provided no indication of increased susceptibility of rabbit fetuses following *in utero* exposure or of rat fetuses/pups following pre-/postnatal exposures. In these studies, developmental/offspring effects were observed only at or above treatment levels which produced maternal/parental toxicity. When assessing chronic dietary exposure, the Agency concluded that the safety factor can be reduced to 3X for the general population, including infants and children (with the exception of the aforementioned female 13 to 50 population subgroup) since the concern for increased susceptibility seen after *in utero* exposure in the developmental study has no bearing on chronic exposure scenarios for persons other than Females 13 to 50. However, since there still remains a data gap for a developmental neurotoxicity study in rats the safety factor was only reduced to 3X.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water

are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to acibenzolar-*S*-methyl in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of acibenzolar-*S*-methyl on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure (at the 99.9th percentile of exposure), from food to acibenzolar-*S*-methyl will occupy 61% of the aPAD for females 13 to 49 years, the only population subgroup of concern for acute dietary exposure (i.e., no significant acute effects relevant to other subgroups were identified in acute toxicity studies for acibenzolar-*S*-methyl). In addition, despite the potential for acute dietary exposure to acibenzolar-*S*-methyl in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of acibenzolar-*S*-methyl in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURETO ACIBENZOLAR-*S*-METHYL

Population Subgroup/	aPAD (mg/kg)	% aPAD/(Food)	Surface Water EEC/(ppb)	Ground Water EEC/(ppb)	Acute DWLOC/(ppb)
Females 13-49 years	0.0033	61	7.9	0.02	39

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to acibenzolar-*S*-methyl from food will utilize 6% of the cPAD for the U.S. population, 3% of the cPAD for all infants less than 1 year old, 12% of the cPAD for children 1 to 2 years old, the children's subpopulation at greatest exposure and 49% of the cPAD for females 13 to 50 years, the subpopulation at greatest risk. There are no residential uses for acibenzolar-*S*-methyl that result in chronic residential exposure to acibenzolar-*S*-methyl. In addition, despite the potential for chronic dietary exposure to acibenzolar-*S*-methyl in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of acibenzolar-*S*-methyl in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO ACIBENZOLAR-*S*-METHYL

Population/Subgroup	cPAD/mg/kg/day	%/cPAD/(Food)	Surface Water EEC/(ppb)	Ground/Water EEC/(ppb)	Chronic/DWLOC (ppb)
U.S. Population	0.0367	6	0.49	0.02	1,200
Infants (<1 year old)	0.0367	3	0.49	0.02	360
Children (1 to 2 years old)	0.0367	12	0.49	0.02	320
Females (13 to 49 years old	0.0033	49	0.49	0.02	50

3. *Short-term and Intermediate-term risks*. Short-term and intermediate-term aggregate exposure take into account non-dietary, and non-occupational plus chronic exposure to food and water (considered to be a background exposure level). Acibenzolar-*S*-methyl is not registered for use on any sites that would result in residential exposure; therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Aggregate cancer risk for U.S. population*. Acibenzolar-*S*-methyl has been classified as not likely to be carcinogenic to humans; therefore, acibenzolar-*S*-methyl is expected to pose at most a negligible 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, and to infants and children from aggregate exposure to acibenzolar-*S*-methyl residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (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

There are no maximum residue limits for acibenzolar-*S*-methyl that have been established by Codex or in Canada or Mexico; therefore, no compatibility issues exist with Codex in regard to the proposed U.S. tolerances discussed in this review.

VI. Conclusion

Therefore, the tolerances are established for residues of acibenzolar-

S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, in or on onion, dry bulb and onion, green at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0214 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 18, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2004–0214, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

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

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 7, 2005.

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 adding text to paragraph (b) to read as follows:

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

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The time-limited tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Onion, dry bulb	0.05	6/30/07
Onion, green	0.05	6/30/07

* * * * *

[FR Doc. 05–2897 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0021; FRL–7697–7]

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of glyphosate, N-(phosphonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on alfalfa, seed. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0021. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of