requirednformation 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 record keeping requirements.

Dated:August 3, 2000.

James Jones,

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 180.415 is amended by adding the commodity ''cranberry'' to the table in paragraph (a) to read as follows:

§ 180.415 Aluminum tris (O–ethylphosphonate); tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Cranberry	0.5	None
* * * * *		

* * * * *

[FR Doc. 00–21081 Filed 8–17–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301037; FRL–6737–6]

RIN 2070–AB78

Acibenzolar-S-Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acibenzolar-*S*-methyl in or on bananas; Brassica (cole) leafy vegetables; fruiting vegetables; tomato, paste; leafy vegetables (except spinach); and spinach. Novartis Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 18, 2000. Objections and requests for hearings, identified by docket control number OPP–301037 must be received by EPA on or before October 17, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301037 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Kenny, Acting PM–22, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7546; and e-mail address: kenny.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1.*Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2.*In person*. The Agency has established an official record for this action under docket control number OPP–301037. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the**Federal Register** of February 18, 1999 (64 FR 8102) (FRL–6061–4) and the**Federal Register** of February 4, 2000 (65 FR 5639) (FRL–6398–9), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) for tolerance by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. These notices included summaries of the petitions prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, in or on bananas at 0.1 part per million (ppm), Brassica (cole) leafy vegetables at 1.0 ppm, fruiting vegetables at 1.0 ppm, leafy vegetables (except spinach) at 0.25 ppm and spinach at 1.0 ppm. Agency review of data submitted in support of the petitions indicated that a separate tolerance of 3.0 ppm for tomato, paste should also be established.

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) 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) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 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).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of acibenzolar-*S*-methyl on bananas at 0.1 ppm; Brassica (cole) leafy vegetables at 1.0 ppm; fruiting vegetables at 1.0 ppm; tomato, paste at 3.0 ppm; leafy vegetables (except spinach) at 0.25 ppm; and spinach at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing the 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. The nature of the toxic effects caused by acibenzolar-*S*-methyl are discussed in this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Guideline No./Study Type	Results
870.3100 90–Day oral toxicity rats	NOAEL: Males:126 mg/kg/day; Females: 131 mg/kg/day LOAEL: Males = 516 mg/kg/day; Females = 554 mg/kg/day based on decreased mean body weights, decreased food consumption and efficiency, and increased liver and spleen weights with correlates of glycogen deposition and hemosiderosis for the liver and spleen, respectively.
870.3150 90–Day oral toxicity dogs	NOAEL = 50 mg/kg/day LOAEL = 200 mg/kg/day based on regenerative hemolytic anemia.
870.3200 21/28–Day dermal toxicity rats	NOAEL = 1,000 mg/kg/day LOAEL = not identified
870.3700a Prenatal developmental rats	Maternal NOAEL = 200 mg/kg/day; LOAEL = 400 mg/kg/day based on hemorrhagic perineal discharge. Developmental NOAEL = not identified (<10 mg/kg/day) LOAEL = 10 mg/kg/day (lowest dose tested) based on umbilical hernia.
870.3700b Prenatal developmental rabbits	Maternal NOAEL = 50 mg/kg/day LOAEL = 300 mg/kg/day based on mortality, clinical signs of toxicity, decreased maternal body weight and food consumption. Developmental NOAEL = 300 mg/kg/day LOAEL = 600 mg/kg/day based on a marginal increase in vertebral anomalies.
870.3800 Reproduction and fertility effects rats	Parental/Systemic NOAEL = 11–31 mg/kg/day LOAEL = 105–288 mg/kg/day based on increased weights and hemosiderosis of the spleen. Reproductive NOAEL = 223–604 mg/kg/day LOAEL >223–604 mg/kg/day based on no effects. Offspring NOAEL = 11–31 mg/kg/day LOAEL = 105–288 mg/kg/day based on reduced pup body weight gains and lower pup body weights during lactation.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No./Study Type	Results
870.4100a Chronic toxicity rats	NOAEL = Males: 96.9 mg/kg/day; Females: 111 mg/kg/day LOAEL = Males: 312 mg/kg/day; Females: 388 mg/kg/day based on decreased body weight, body weight gain and food efficiency, mild hemolytic anemia, and increased incidence of alveolar foam cells (females only).
870.4100b Chronic toxicity dogs	NOAEL = 25 mg/kg/day LOAEL = 200 mg/kg/day based on effects consistent with hemolytic anemia, including hematological effects, hemosiderosis of the liver and spleen, extramedullary hematopoiesis of the spleen, and increased liver weights.
870.4200a Carcinogenicity rats	NOAEL = Males: 96.9 mg/kg/day; Females: 111 mg/kg/day LOAEL = Males: 312 mg/kg/day; Females: 388 mg/kg/day based on decreased body weight, body weight gain and food efficiency, mild hemolytic anemia, and increased incidence of alveolar foam cells (females only). No evidence of carcinogenicity
870.4200b Carcinogenicity mice	NOAEL = Males:11.1 mg/kg/day; Females: 10.8 mg/kg/day LOAEL = Males: 237 mg/kg/day; 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. No evidence of carcinogenicity
870.5100 Bacterial reverse mutation assay (Ames test)	Negative with and without S–9 activation at 5000 μg/plate and less.
870.5100 Bacterial reverse mutation assay (Ames test) Test Material: CGA–362020 (isomer of acibenzolar-*S*-methyl)	Positive in *S. typhimurium* strain TA1537 at 277.8 μg/plate and higher in the absence of S–9. Negative with S–9 activation at 5000 μg/plate and less.
870.5100 Bacterial reverse mutation assay (Ames test) Test Material: NOA–419191 (by-product of acibenzolar-*S*-methyl)	Negative with or without S–9 activation at 5000 μg/plate and less
870.5100 Bacterial reverse mutation assay (Ames test) Test Material: CGA–323060 (plant metabolite of acibenzolar-*S*-methyl)	Negative with or without S–9 activation at 5000 μg/plate and less
870.5300 *In vitro* mammalian gene mutation assay	Negative with S–9 activation up to 1000 μg/ml. Negative without S–9 activation up to 100 μg/ml. Compound tested to cytotoxic concentrations.
870.5375 *In vitro* mammalian chromosome aberration (CHO cells)	Suggestive of clastogenicity in the absence of S–9 activation at 30 and 60 μg/mL at the 18–hour cell harvest time; effect observed only in the presence of cytotoxicity. Increase in polyploid cells at 30 and 60 μg/mL at the 42 hour harvest time both with and without S– 9. Evidence of cell cycle arresting activity at G2.
870.5395 Mammalian erythrocyte micronucleus test	Negative at 16, 24, and 48, hour sacrifices.
870.5550 UDS in primary rat hepatocytes	Negative at 500 μg/ml and less.
870.7485 Metabolism and pharmacokinetics rats	Following oral treatment of rats, acibenzolar-*S*-methyl was rapidly and nearly completely (>90% of administered dose) absorbed from the gastrointestinal tract into the general circulation. The majority (88–95%) of the administered dose was excreted in the urine within the first 48 hours. The major metabolite (79–92%) in the urine was the carboxylic acid derivative of the parent.
Special studies: 28–Day dietary rats	NOAEL = M: 403 mg/kg/day; F: 376 mg/kg/day LOAEL = M: 1070 mg/kg/day; F: 1,000 mg/kg/day based on decreased mean body weights, decreased liver weights, altered hematology parameters accompanied by increased spleen weights.
28–Day oral gavage rats	NOAEL = 100 mg/kg/day LOAEL = 800 mg/kg/day based on decreased body weights, and decreased hemoglobin-related parameters accompanied by hemosiderosis of the spleen, increased liver and spleen weights, and decreased thymus weights.
28–Day oral capsule dogs	NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on decreased body weight, decreased hemoglobin-related parameters, hepatic and splenic hemosiderosis.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No./Study Type	Results
90–Day Dietary mice	NOAEL = M: 30.6 mg/kg/day; F: 47.4 mg/kg/day;
	LOAEL = M: 152 mg/kg/day; F: 220 mg/kg/day based on decreased mean body weights and body weight gain in males, increased spleen weights and splenic histopathology in both sexes.
Special Developmental toxicity rats	Maternal and developmental NOAELS and LOAELS could not be identified by this protocol. The most pronounced maternal and developmental toxicity occurred when dams were treated on GD 6–15.
Special Developmental toxicity rats	Maternal and developmental NOAELS and LOAELS could not be identified by this protocol. The most pronounced maternal and developmental toxicity occurred when dams were treated on GD 6–7 and 8–9.
Dermal developmental toxicity rats	Maternal NOAEL ≥500 mg/kg/day LOAEL >500 mg/kg/day based on no effects. Developmental NOAEL ≥500 mg/kg/day LOAEL >500 mg/kg/day based on no effects.
Range-finding 1-generation reproduction rats	Parental/Systemic NOAEL = 209 mg/kg/day LOAEL = 410 mg/kg/day based on decreased body weight gain and food consumption in females. Reproductive NOAEL = 410 mg/kg/day LOAEL = 728 mg/kg/day based on total resorptions in all dams. Offspring NOAEL = 209 mg/kg/day LOAEL = 410 mg/kg/day based on reduced pup body weight gains and lower pup body weights during lactation.

B. Toxicological Endpoints

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 level of concern (LOC). 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 intra species 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 Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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.

TABLE 2.—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[1] and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age.	LOAEL = 10 mg/kg/day UF = 300 Acute RfD = 0.033 mg/kg/day	FQPA SF = 10; aPAD = acute RfD ÷ FQPA SF = 0.0033 mg/kg/day	Developmental toxicity - rats; LOAEL = 10 mg/kg/day based on increased incidence of rare malformations (umbilical hernias).
Chronic Dietary females 13–50 years of age.	LOAEL = 10 mg/kg/day UF = 300 Acute RfD = 0.033 mg/kg/day	FQPA SF = 10 aPAD = acute RfD ÷ FQPA SF = 0.0033 mg/kg/day	Developmental toxicity - rats; LOAEL = 10 mg/kg/day based on increased incidence of rare malformations (umbilical hernias).

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ACIBENZOLAR-S-METHYL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF[1] and Level of Concern for Risk Assessment	Study and Toxicological Effects
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 - 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.

[1] The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have previously been established for acibenzolar-*S*-methyl. 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 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. After a Tier I acute dietary analysis based on tolerance level residues and assuming 100 percent crop treated resulted in risk estimates that were unacceptably high, a probabilistic (i.e., Monte Carlo) acute dietary exposure assessment was performed using the distribution of residues observed in the crop field trials and projected percent market share information (leafy vegetables,16%; fruiting vegetables 14%; brassica vegetables (2%). The refined analysis estimated acute dietary exposure of females, 13–50 years old, to acibenzolar-*S*-methyl at the 99.9th percentile of exposure.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: that residues would be present in or on treated crops at tolerance levels and that 100% of crops would be treated.

iii. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) 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 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. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows:

A probabilistic (i.e., Monte Carlo) acute dietary risk assessment for acibenzolar-*S*-methyl was based on the following PCT projections: leafy vegetables (16%); fruiting vegetables (14%); brassica vegetables (2%).

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described above for acibenzolar-*S*-methyl on leafy vegetables, fruiting vegetables and brassica 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. Based on available information, including the petitioner's research and experience in these markets, information on other registered pesticides, and prevalence of target weeds, EPA believes the petitioner's estimates do not underestimate the percent of these crops that may be treated. As to Conditions 2 and 3, 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 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 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, 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 that 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 GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of acibenzolar-*S*-methyl in surface water and ground water for acute exposures are estimated to be 0.64 parts per billion (ppb) for surface water and negligible for ground water. The EECs for chronic exposures are estimated to be 0.02 ppb for surface water and negligible 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) 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 does not have, at this time, available data to determine whether acibenzolar-*S*-methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *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 data base 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 uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *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.

iii. *Conclusion*. The toxicology database for Acibenzolar-*S*-Methyl is incomplete. Subchronic neurotoxicity, developmental neurotoxicity and an additional mutagenicity study (Ames study) are required. The Agency concluded that the FQPA Safety Factor be retained at 10X based on (1) 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); (2) 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; (3) 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 toxicity study; and (4) the potential for the requested uses of acibenzolar-*S*-methyl to result in acute and chronic dietary exposure. When assessing acute and chronic dietary exposures, the Agency concluded that the FQPA safety factor should be retained at 10X for the female, 13–50 years old, population subgroup (the only population subgroup of concern for acute exposures). When assessing chronic dietary exposure, however, the Committee 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 13–50 population subgroup) since there is no concern for increased susceptibility due to*in utero* exposure for persons other than females 13–50, but there still remains a data gap for a developmental neurotoxicity study in rats.

E. 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 + residential 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: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Actual 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, OPP concludes with reasonable certainty that exposures to the pesticide 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 residues of the pesticide in 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 87% of the aPAD for females 13 years and older, 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, there is potential for acute dietary exposure to acibenzolar-*S*-methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO ACIBENZOLAR-S-METHYL

Population Subgroup	a PAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years	0.0033	87	0.64	Negligible	12

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, 52% of the cPAD for females 13 to 50 years old, 3% of the cPAD for infants less than 1 year old and 11% of the cPAD for children 1 to 6 years old, the subgroup of children with the highest estimated food exposure to acibenzolar-*S*-methyl. There are no residential uses for acibenzolar-*S*-methyl that result in chronic residential exposure to acibenzolar-*S*-methyl. In addition, there is potential for chronic dietary exposure to acibenzolar-*S*-methyl in drinking water. After calculating the DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

TABLE 4.—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	0.02	negligible	1200
All Infants 1 year	0.0367	3	0.02	negligible	360
Children 1–6 years	0.0367	11	0.02	negligible	320
Females 13–50 years	0. 0033	52	0.02	negligible	50

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure 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 do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure 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 do not exceed the Agency's level of concern.

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.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a residue analytical method for tolerance

enforcement that uses liquid chromatography with UV detection (HPLC-UV). This method is currently being validated by the Analytical Chemistry Branch laboratories, BEAD (7503C), Office of Pesticide Programs. Upon successful completion of the EPA validation and the granting of this registration the method will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual, Vol-II (PAM-II). Prior to publication in PAM-II and upon request, the method will be available prior to the harvest season from the Analytical Chemistry Branch (ACB), BEAD (7503C), Environmental Science Center, 701 Mapes Road, Ft George G. Meade, MD 20755–5350; contact Francis D. Griffith, Jr, telephone (410) 305–2905, e-mail griffith.francis@epa.gov. The analytical standards for this method are also available from the EPA National Pesticide Standard Repository at the same location.

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.

C. Conditions

The registration of acibenzolar-*S*-methyl will be conditioned upon submission of the following toxicology studies: Developmental neurotoxicity study in rats; subchronic neurotoxicity study in rats; and an additional mutagenicity study (Ames test).

V. Conclusion

Therefore, tolerances are established for residues of acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, in or on bananas at 0.1 ppm; Brassica (cole) leafy vegetables at 1.0 ppm; fruiting vegetables at 1.0 ppm; tomato, paste at 3.0 ppm; leafy vegetables (except spinach) at 0.25 ppm; and spinach at 1.0 ppm

VI. 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301037 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 17, 2000.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301037, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). 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 prior consultation as specified by Executive Order 13084, entitled*Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled*Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled*Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: August 9, 2000.

Joseph J. Merenda

Acting Director, 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 added to read as follows:

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

(a) *General.* 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
Bananas[1]	0.1
Brassica (cole) leafy vegetables	1.0
Fruiting vegetables	1.0
Leafy vegetables	0.25
Spinach	1.0
Tomato, paste	3.0

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

(b)*Section 18 emergency exemptions.* [Reserved]

(c)*Tolerances with regional registrations.* [Reserved]

(d)*Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00–21080 Filed 8–17–00; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3500

[WO–320–1990–01–24 A]

RIN 1004–AC49

Leasing of Solid Minerals Other Than Coal and Oil Shale

AGENCY: Bureau of Land Management, Interior.

ACTION: Direct final rule.

SUMMARY: On April 28, the Mineral Leasing Act was effectively amended to change the acreage limits on a Bureau of Land Management (BLM) customer who leases public lands and minerals to produce sodium. The new law increased the maximum number of acres a person can lease in any one state from 15,360 acres in any one state to 30,720 acres. This rule revises the regulations of the BLM to reflect the new law.

DATES: This direct final rule is effective on October 17, 2000 without further notice, unless BLM receives adverse comment by September 18, 2000. If adverse comment is received, BLM will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: You may mail comments to Bureau of Land Management, Administrative Record, Room 401 LS, 1849 C Street, NW, Washington, D.C. 20240. You may also hand-deliver comments to BLM at Room 401, 1620 L Street, NW, Washington, D.C. For information about filing comments electronically, see the **SUPPLEMENTARY**