List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Lead, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 20, 2000.

Francis X. Lyons,

Regional Administrator, Region 5.

For the reasons stated in the preamble, title 40, Chapter I of the Code of Federal Regulation are amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart P—Indiana

2. Section 52.797 is amended by removing the introductory text and adding paragraph (d) to read as follows:

§ 52.797 Control strategy: Lead.

* * * * *

(d) On March 2, 2000, Indiana submitted a maintenance plan for Marion County as part of its request to redesignate the County to attainment of the lead standard.

* * * * *

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart C—Section 107 Attainment Status Designations

2. The table in § 81.315 entitled ''Indiana Lead'' is amended to read as follows:

§ 81.315 Indiana.

* * * * *

INDIANA—LEAD

Designated area	Designation		Classification	
	Date	Type	Date	Type
Marion County (Part)—Part of Franklin Township: Thompson Road on the south; Emerson Avenue on the west; Five Points Road on the East; and Troy Avenue on the north.	July 10, 2000	Attainment.		
Marion County (Part)—Part of Wayne Township: Rockville Road on the north; Girls School Road on the east; Washington Street on the south; and Bridgeport Road on the west.	July 10, 2000	Attainment.		
Rest of State Not Designated.				
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[FR Doc. 00–11423 Filed 5–9–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300994; FRL–6555–5]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of myclobutanil in or on a variety of food commodities. Rohm and Haas Company and the Interregional Research Project #4 (IR–4) 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 May 10, 2000. Objections and requests for hearings, identified by docket control number OPP–300994, must be received by EPA on or before July 10, 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–300994 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; and e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you sell, distribute, manufacture, or use pesticides for agricultural applications, process food, distribute or sell food, or implement governmental pesticide regulations. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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'' 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–300994. 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 September 2, 1999 (64 FR 48165) (FRL–6049–5), EPA issued a notice 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 tolerances by Rohm and Haas Company and IR–4. This notice included a summary of the petitions prepared by Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.443 be amended by establishing tolerances for combined residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and its alcohol metabolite (alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on the following commodities:

1. *PP 7E4862*. IR–4 proposes the establishment of a tolerance for asparagus at 0.02 parts per million (ppm).

2.*PP 7E4866*. IR–4 proposes the establishment of a tolerance for the caneberry subgroup at 1.0 ppm. The petition was subsequently amended to propose the establishment of a tolerance for the caneberry subgroup at 2.0 ppm.

3. *PP 8E4939*. IR–4 proposes the establishment of tolerances for currant at 3.0 ppm and gooseberry at 2.0 ppm.

4. *PP 7E4877*. IR–4 proposes the establishment of a tolerance for mint at 3.0 ppm. The petition was revised to specify peppermint and spearmint tops at 3.0 ppm.

5. *PP 7E4861*. IR–4 proposes the establishment of a tolerance for snap beans at 1.0 ppm. The petition was amended to proposed a tolerance for succulent snap bean at 1.0 ppm.

6. *PP 4E4302*. IR–4 proposes the establishment of a tolerance for strawberry at 0.5 ppm.

7. *PP 1F4030*. Rohm and Haas Company proposes the establishment of tolerances for tomato at 0.3 ppm, tomato puree at 0.6 ppm and tomato paste at 1.2 ppm. The petition was subsequently amended to propose tolerances for tomato at 0.3 ppm, tomato puree at 0.5 ppm and tomato paste at 1.0 ppm.

8. *PP 9F3812*. Rohm and Haas Company proposes the establishment of a tolerance for the pome fruit group at 0.5 ppm. The petition was amended to propose a tolerance for mayhaw at 0.7 ppm and apple wet pomace at 1.3 ppm.

9. *PP 2F4155*. Rohm and Haas Company proposes the establishment of tolerances for the cucurbit vegetables group at 0.5 ppm. The petition was amended to propose a tolerance for the cucurbit vegetables group at 0.2 ppm. The petition was also amended to propose tolerances for indirect and inadvertent residues of myclobutanil (parent compound only) at 0.03 ppm for the following rotational crop groups: root and tuber vegetables group; leaves of root and tuber vegetables group; leafy vegetables (except Brassica vegetables) group; Brassica leafy vegetables group; legume vegetables group; foliage of legume vegetables group; fruiting vegetables group; cereal grains group; forage, fodder and straw of cereal grains group; and the nongrass animal feeds group.

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 food and 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 myclobutanil on the named commodities. 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 myclobutanil 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.— TOXICITY PROFILE OF MYCLOBUTANIL TECHNICAL

Guideline/Study	Results
82–1(a) Subchronic Feeding in Rats (13 weeks)	NOAEL: 1000 ppm LOAEL: 3000 ppm based on increased liver, kidney weights; hypertrophy, necrosis in liver; pigmentation in convoluted kidney tubules; vacuolated adrenal cortex.
82–1(a) Subchronic Feeding in Mice (13 weeks)	NOAEL: 45 mg/kg/day(300 ppm) LOAEL: 150 mg/kg/day (1000 ppm) based on hepatocytic hypertrophy, swollen-vacuolated centrilobular hepatocytes, single large hepatocyte vacuoles, centrilobular individual cell hepatocyte necrosis and centrilobular necrotic hepatitis; cytoplasmic eosinophilia and/or hypertrophy of the zona fasculata cells of the adrenal glands of males.
82–1(b) Subchronic Feeding in Dogs (13 Weeks)	NOAEL: 5 mg/kg/day (200 ppm) LOAEL: 20 mg/kg/day (800 ppm) based on liver changes including increased alkaline phosphatase, relative and absolute liver weight and hepatocellular hypertrophy.
82–2 28–day Dermal Toxicity in Rats	NOAEL for systemic effects: greater than 100 mg a.i./kg/day (the highest dose in both studies) LOAEL: not established NOTE: this was conducted in 2 formulations rather than the technical (40WP - 41.36%; 2EC - 24.99%).
83–1(b) Chronic Feeding Study in Dogs	NOAEL: 3.09 mg/kg/day (100 ppm) LOAEL: 14.28 mg/kg/day (400 ppm) based on hepatocellular hypertrophy, increases in liver weights, ''ballooned'' hepatocytes and increases in alkaline phosphatase, SGPT and GGT. In addition, there were some possible slight hematological effects.
83–2(b) Carcinogenicity study in mice	NOAEL: 13.7 mg/kg/day (100 ppm) for males LOAEL: 70.2 mg/kg/day (500 ppm in males); not established in females. There were increased MFO (males and females); increased SGPT (females) & increased absolute & relative liver weights (males and females); increased incidences and severity of centrilobular hepatocytic hypertrophy, Kupffer cell pigmentation, periportal punctate vacuolation & individual hepatocellular necrosis (males); and increased incidences of focal hepatocellular alterations and multifocal hepatocellular vacuolation (males and females). Not tested at high enough dose levels in females. In a second carcinogenicity study in mice, female mice were tested at sufficiently high dose levels (2000 ppm (393.5 mg/kg/day)), no carcinogenic effects observed.
83–2(b) Carcinogenicity study in mice	NOAEL: Not established LOAEL: 2000 ppm (393.5 mg/kg/day) (only dose tested) based on decreases in body weight and body weight gain; increases in liver weights; hepatocellular hypertrophy; hepatocellular vacuolation; necrosis of single hypertrophied hepatocytes; yellow-brown pigment in the Kupffer cells and cytoplasmic eosinophilia and hypertrophy of the cells of the zona fasciculata area of the adrenal cortex. Not carcinogenic under the conditions of the study.
83–5 Chronic Feeding/carcinogenicity study in rats	NOAEL: 2.49 mg/kg/day (50 ppm) LOAEL: 9.94 mg/kg/day (200 ppm) based on decreased testes weights and increased testicular atrophy. Not tested at high enough dose levels. In a second chronic feeding/carcinogenicity study in rats, rats were tested at sufficiently high dose levels (2500 ppm: 125 mg/kg/day), no carcinogenic effects observed.
83–5 Chronic feeding/carcinogenicity study in rats	NOAEL: Not established LOAEL: 125 mg/kg/day (2500 ppm) (only dose tested) based on testicular atrophy and decreases in testes weights; increases in the incidences of centrilobular to midzonal hepatocellular enlargement and vacuolization in the liver of both sexes; increases in bilateral aspermatogenesis in the testes; increases in the incidence of hypospermia and cellular debris in the epididymides; and increased incidence of arteritis/periarteritis in the testes). No carcinogenic effects observed.
83–3(a) Developmental Toxicity Study in Rats	Maternal NOAEL: 93.8 mg/kg/day Maternal LOAEL: 312.6 mg/kg/day based on rough hair coat and salivation at 312.6 mg/kg/day and salivation, alopecia, desquamation and red exudate around mouth at 468.87 mg/kg/day. Developmental NOAEL: 93.8 mg/kg/day Developmental LOAEL: 312.6 mg/kg/day based on increased incidences of 14th rudimentary and 7th cervical ribs at 312.6 and 468.9 mg/kg/day.
83–3(b) Developmental Toxicity Study in Rabbits	Maternal NOAEL: 60 mg/kg/day Maternal LOAEL: 200 mg/kg/day based on reduced body weight and body weight gain during the dosing period, clinical signs of toxicity and possibly abortions. Developmental NOAEL: 60 mg/kg/day Developmental LOAEL: 200 mg/kg/day based on increases in number of resorptions, decreases in litter size and a decrease in the viability index.

TABLE 1.— TOXICITY PROFILE OF MYCLOBUTANIL TECHNICAL—Continued

Guideline/Study	Results
83–4 2-Generation Reproduction Toxicity in Rats	Systemic NOAEL: 2.5 mg/kg/day (50 ppm) Systemic LOAEL: 10 mg/kg/day (200 ppm) based on increased liver weights and hepatocellular hypertrophy. Reproductive NOAEL: 10 mg/kg/day (200 ppm) Reproductive LOAEL: 50 mg/kg/day (1000 ppm) based on increased incidence in the number of stillborns and atrophy of the testes, epididymides and prostate. Developmental NOAEL: 10 mg/kg/day (200 ppm) Developmental LOAEL: 1000 ppm (50 mg/kg/day) based on decrease in pup body weight gain during lactation.
84–2 Gene Mutation Assay (Ames Test)	No appreciable increase in the reversion to histidine protrophy of 4 *S. typhimurium*strains at 75 to 7500 µg/plate with & without S–9 activation.
84–2 Gene Mutation Assay Mammalian Cells	Negative with and without metabolic activation up to 175 µg/ml.
84–2 Structural Chromosomal Aberration Assay *In vivo*cytogenetics.	The level of 650 mg/kg did not cause a significant increase in chromosomal aberrations in bone marrow cells sampled over the entire mitotic cycle.
84–2 Structural Chromosomal Aberration Assay *In vitro*cytogenetics.	Did not induce chromosomal aberrations with & without metabolic activation under the conditions of the study up to 200 µg/ml.
84–2 Structural Chromosomal Aberration Assay Dominant Lethal Test.	Did not induce dominant lethal mutations under conditions of study at dose levels up to 735 mg/kg.
84–2 Other Genotoxicity Assays (Unscheduled DNA Synthesis).	Did not induce an increase in unscheduled DNA synthesis up to toxic dose. 0.1–1000 µg/ml tested.
85–1 Metabolism	Rapidly absorbed and excreted. Completely eliminated by 96 hrs. Extensively metabolized prior to excretion. Metabolic patterns similar for both sexes. Disposition & metabolism after pulse administration is linear over dose range.
85–1 Metabolism	Completely and rapidly absorbed. Extensively metabolized and rapidly and essentially completely excreted. Elimination of label from plasma biphasic and evenly distribution between urine and feces. No tissue accumulation after 96 hours.
85–1 Metabolism	At least 7 major metabolites recovered and identified. Highest amounts of radioactivity found in liver, kidneys, large and small intestines. No tissue accumulation.
85–2 Dermal Absorption	Although this study is considered unacceptable, the potential dermal absorption is not expected to be greater than 50%.

B. Toxicological Endpoints

The dose at which 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 intra species differences.

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 (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.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MYCLOBUTANIL FOR UES IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint for Risk Assessment[1]	Study and Toxicological Effects
Acute Dietary females 13–50 years of age.	NOAEL = 60 mg/kg/day UF = 100 Acute RfD = 0.60 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = [0.60] mg/kg/day.	Developmental Toxicity - rabbit LOAEL = 200 mg/kg/day based on increased resorptions, decreased litter size and a decrease in the viability index.
Acute Dietary general population including infants and children.	none	not applicable	not applicable
Chronic Dietary all populations	NOAEL = 2.49 mg/kg/day UF = 100 ..... Chronic RfD = 0.025 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.025 mg/kg/day.	Chronic Toxicity/Carcinogenicity - rat LOAEL = 9.94 mg/kg/day based on decreased testicular weights and increased testicular atrophy.
Short-Term Dermal (1 to 7 days) Residential.	dermal study NOAEL = 100 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	28–day Dermal Toxicity-rat LOAEL = > 100 mg/kg/day based on no signs of toxicity at the high dose of 100 mg/kg a.i.
Intermediate-Term Dermal (1 week to several months) Residential.	oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 50%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2 Generation Reproduction Toxicity - rat LOAEL = 50 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation.
Long-Term Dermal (several months to lifetime) Residential.	oral study NOAEL= 2.49 mg/kg/day (dermal absorption rate = 50%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	Chronic Toxicity/Carcinogenicity - rat LOAEL = 9.94 mg/kg/day based on decreased testicular weights and increased testicular atrophy.
Short-Term Inhalation (1 to 7 days) Residential.	oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2 Generation Reproduction Toxicity - rat LOAEL = 50 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation
Intermediate-Term Inhalation (1 week to several months) Residential.	oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2 Generation Reproduction Toxicity - rabbit LOAEL = 50 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation.
Long-Term Inhalation (several months to lifetime) Residential.	oral study NOAEL= 2.49 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	chronic Toxicity/Carcinogenicity - rat LOAEL = 9.94 mg/kg/day based on decreased testicular weights and increased testicular atrophy.
Cancer (oral, dermal, inhalation).	''Group E''	not applicable	not applicable

[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.* Tolerances have been established (40 CFR 180.443) for the combined residues of myclobutanil, in or on a variety of raw agricultural commodities. Permanent tolerances are established for the combined residues of myclobutanil and its alcohol metabolite (free and bound) in or on a variety of commodities at levels ranging from 0.02 to 25.0 ppm and in meat, milk, poultry, and eggs at levels ranging from 0.02 to 1.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures from myclobutanil 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. The following assumptions were made for the acute exposure assessments: A tier 1 acute

analysis was performed using tolerance level residues and 100% crop treated (CT) information for all registered and proposed uses. The acute analysis was performed for females (13–50 years old) only (no acute endpoint was chosen for the general U.S. population).

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis was performed using published and proposed tolerance levels for all commodities. For the chronic analysis, percent CT information was used for apples, apricots, cherries, grapes, nectarines, peaches, pears, plums, and cotton and 100% CT was assumed for all other commodities.

iii.*Cancer*. A cancer dietary exposure assessment was not performed since myclobutanil was not carcinogenic in two acceptable animal studies.

iv. *Anticipated residue and percent crop treated information*. 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.

Crop	Percent crop treated
Apples	40
Apricots	15
Cherries	40
Cotton	<1
Grapes	45
Nectarines	20
Peaches	10
Pears	< 1
Plums	15

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. 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 myclobutanil may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive drinking water dietary exposure analysis and risk assessment for myclobutanil 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 myclobutanil.

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 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 myclobutanil, they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models, the estimated environmental concentrations (EECs) of myclobutanil for acute exposure are estimated to be

115 parts per billion (ppb) in surface water and 2 ppb for ground water. The EECs for chronic exposures are estimated to be 31 ppb for surface water and 2 ppb for ground water.

3. *From non-dietary exposure.* Myclobutanil is currently registered for use on the following residential non-dietary sites: homeowner use on turf, roses, flowers, shrubs and trees. The term ''residential exposure'' is used in this document to refer to non-occupation, nondietary exposure resulting from pesticide uses in residential settings (e.g., pesticide uses for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets.) The risk assessment was conducted using the following exposure assumptions:

i. *Residential handler exposure.* Based on the residential use-patterns associated with myclobutanil, there is potential for exposures to handlers of myclobutanil. In order to present a high-end scenario of residential exposure, it was assumed that one person would complete all mixing, loading and application of myclobutanil. Exposure scenarios were assessed, at the maximum application rate, for mixing, loading, and application of a soluble concentrate product by trigger bottle sprayer (treating ornamental plants), and by hose-end sprayer (treating turfgrass) to represent the worst-case scenario for the proposed uses. There are no chemical specific data available to support the residential use scenarios of myclobutanil. Therefore, modeling (PHED v 1.1 surrogate table) was used to represent the highest potential for exposure from homeowner application of myclobutanil.

ii. *Residential post application exposure.* Potential residential exposures are expected following applications to lawns, ornamentals and home garden sites. Chemical-specific data are available to determine the potential risks from post-application activities. The registrant submitted a dislodgeable foliar residue (DFR) study on grapes for myclobutanil. Short-term post-application exposure estimates were done using the study determined DFR of 0.175 $\mu g/cm^2$ (on day 0). For intermediate-term post-application exposure, an average of DFRs from day 0 through day 14 was used. The post-application risk assessment is based on DFR data from the submitted study on grapes and generic assumptions as specified by the recently revised Residential SOPs.

Based on the use pattern, exposure to myclobutanil-treated ornamentals is expected to be incidental and short-term. Both short- and intermediate-term exposures are expected following lawn applications of myclobutanil. Short-term aggregate post-application exposure for the adult was done for dermal exposure to treated turf and ornamentals. Since there is no intermediate-term exposure for the residential handler, there is no aggregate intermediate-term exposure for the adult.

Short-term, non-dietary ingestion exposure to toddlers is not assessed since EPA did not detect an acute dietary or oral endpoint applicable to infants and children. Therefore, EPA does not expect short-term non-dietary exposure to pose a risk to infants and children. The only short-term toddler exposure that was considered consists of dermal post-application exposure. However, EPA determined that the short-term dermal exposure should not be aggregated with the short-term oral exposure because the toxic effects are different.

Additionally, intermediate-term, non-dietary ingestion exposure for toddlers is possible and was assessed using the intermediate-term dose and endpoint identified from the two generation reproduction toxicity study in rats. Intermediate-term aggregate exposure for toddlers combines non-dietary ingestion and dermal exposure from treated turf.

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 myclobutanil 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, myclobutanil 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 myclobutanil 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 based 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 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.* There was no evidence of increased susceptibility in the developmental toxicity studies with rats and rabbits. The data from the 2-generation reproduction study in rats provided no indication of quantitative or qualitative increased susceptibility since maternal toxicity and reproductive toxicity occurred at the same dose.

iii. *Conclusion.* There is a complete toxicity data base for myclobutanil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because:

a. There are no toxicity or residential exposure data gaps in the consideration of the FQPA Safety Factor.

b. There was no evidence of increased susceptibility in the developmental toxicity studies with rats and rabbits and the 2-generation reproduction study in rats provided no indication of quantitative or qualitative increased susceptibility since maternal toxicity and reproductive toxicity occurred at the same dose.

c. A developmental neurotoxicity study is not required because neurotoxic compounds of similar structure were not identified and there was no evidence of neurotoxicity in the current toxicity database.

d. The exposure assessments will not underestimate the potential dietary (food and drinking water) and residential (non-occupational) exposures for infants and children from the use of myclobutanil.

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 + 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: 2L/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, OPP concludes with reasonable certainty that exposures to myclobutanil 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 myclobutanil 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 from food to myclobutanil will occupy 2% of the aPAD for females 13 years and older at the 95th percentile of exposure. In addition, despite the potential for acute dietary exposure to myclobutanil in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of myclobutanil in surface and ground water (115 ppb and 2 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO MYCLOBUTANIL

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13 to 50 years)	0. 60	2	115	2	18,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to myclobutanil from food will utilize 17% of the cPAD for the U.S. population, 48% of the cPAD for infants < 1 year old and 52% of the cPAD for children 1 to 6 years old. There are no residential uses for myclobutanil that result in chronic residential exposure. In addition, despite the potential for chronic dietary exposure to myclobutanil in drinking water, after calculating the DWLOCs and comparing them to conservative model estimated environmental concentrations of myclobutanil in 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 MYCLOBUTANIL

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.025	17	31	2	720
All Infants (<1 year old)	0.025	48	31	2	130
Children 1 to 6 years	0.025	52	31	2	120
Children 7 to 12 years	0.025	26	31	2	190
Females (13 to 50 years)	0.025	11	31	2	670

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). EPA has determined that oral and dermal exposures can not be aggregated due to differences in the toxicological endpoints via the oral (developmental study) and dermal routes. Therefore, short-term aggregate risk is captured by assessment of acute risk above.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 650 for the U.S. population and 310 for infants and children. These aggregate MOEs do not exceed the Agency's level of concern (LOC = 100) for aggregate exposure to food and residential uses. In addition, DWLOCs were calculated to account for the potential of intermediate-term exposure to myclobutanil in drinking water. After calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of myclobutanil in surface and ground water (31 ppb and 2 ppb, respectively), EPA does not expect the intermediate-term aggregate exposure to exceed the Agency's level of concern.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO MYCLOBUTANIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
U.S. Population	605	100	31	2	3,000
Infants and Children	310	100	31	2	680

6. *Aggregate cancer risk for U.S. population*. Myclobutanil is not carcinogenic in either the rat or mouse and, therefore, is not expected to pose a cancer risk to humans.

7. *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 myclobutanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method (Rohm and Haas Method 34S–88–10) is available to enforce the proposed tolerances. Quantitation is by gas liquid chromatography using a nitrogen/phosphorus detector for myclobutanil and an electron capture detector (Ni^{63}) for residues measured as the alcohol metabolite. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

A Codex maximum residue limit (MRL) is presently established for residues of myclobutanil per se in/on pome fruit at 0.5 ppm. Canadian MRLs have been established for residues of (RS)-2-*p*-chlorophenyl-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile, including the free and conjugated forms of its metabolites (RS)-2-*p*-chlorophenyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)-5-hydroxy-hexanenitrile and (RS)-2-*p*-chlorophenyl-2-(1*H*-1,2,4-triazol-1ylmethyl)-5-keto-hexanenitrile on apples and apple juice at 0.5 ppm. No Mexican MRLs have been established for the use on mayhaw. Harmonization with Codex or the Canadian MRLs is not possible as the tolerance expressions for both differ from the proposed U.S. tolerance.

C. Conditions

Rohm and Haas has requested conditional registration for caneberry, currant, gooseberry, mayhaw, peppermint, spearmint, snap beans, and tomato. Upon receipt and evaluation of additional residue field trials for these crops, the Agency will reassess the registration and, if appropriate, will issue unconditional registration for these uses. In addition, the registration on cucurbits, mint, snap beans, strawberries and tomatoes will be conditional pending the submission and EPA review of a field rotational crop study.

V. Conclusion

Therefore, tolerances are established for combined residues of myclobutanil in apple, wet pomace at 1.3 ppm; asparagus at 0.02 ppm; the caneberry subgroup at 2.0 ppm, the cucurbit vegetable group at 0.20 ppm, currant at 3.0 ppm, gooseberry at 2.0 ppm, mayhaw at 0.70 ppm; peppermint tops at 3.0 ppm, succulent snap bean at 1.0 ppm; spearmint tops at 3.0 ppm, strawberry at 0.50 ppm, tomato at 0.30 ppm; tomato, puree at 0.50 ppm; tomato, paste at 1.0 ppm. In addition tolerances for indirect and inadvertent residues of myclobutanil per se at 0.03 ppm are established in root and tuber vegetable group; leaves of root and tuber vegetable group; leafy vegetable, except Brassica, group; Brassica leafy vegetable group; legume vegetable group; fruiting vegetable group; cereal grains group; forage, fodder, and straw of cereal grains group; nongrass animal feed group; and foliage of legume vegetable group.

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 300994 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 July 10, 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, Ariel Rios Bldg., 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, 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, Ariel Rios Bldg., 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, Ariel Rios Bldg., 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–300994, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 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 tolerances under FFDCA section 408(d) in response to petitions 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 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 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: April 28, 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 180.443 is amended by revising the introductory text of paragraph (a), by adding alphabetically new entries to the table in paragraph (a), and by revising paragraph (d) the read as follows:

§ 180.443 Myclobutanil; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and its alcohol metabolite (alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on the following food commodities:

Commodity	Parts per million
* * * * *	
Apple, wet pomace	1.3
* * * * *	
Asparagus	0.02
* * * * *	
Bean, snap, succulent	1.0
Caneberry subgroup	2.0
* * * * *	
Currant	3.0
* * * * *	
Gooseberry	2.0
* * * * *	
Mayhaw	0.70
* * * * *	
Peppermint, tops	3.0
* * * * *	
Spearmint, tops	3.0
Strawberry	0.50
* * * * *	
Tomato	0.30
Tomato, puree	0.50
Tomato, paste	1.0
Vegetable, cucurbit, group	0.20

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile in or on the following food commodities:

Commodity	Parts per million
Animal Feed, Nongrass, Group	0.03
Grains, Cereal, Forage, Fodder, and Straw, Group	0.03
Grains, Cereal, Group	0.03
Vegetable, Brassica, Leafy, Group	0.03
Vegetable, Foliage of Legume, Group	0.03
Vegetable, Fruiting, Group	0.03
Vegetable, Leafy, Except Brassica, Group	0.03
Vegetable, Leaves of Root and Tuber, Group	0.03
Vegetable, Legume, Group	0.03
Vegetable, Root and Tuber, Group	0.03

[FR Doc. 00–11571 Filed 5–9–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6600–4]

West Virginia: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: West Virginia has applied to EPA for Final authorization of the revision to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The revision covers statutory and regulatory changes to the State's authorized hazardous waste program, including the adoption of the Federal hazardous regulations, as amended through June 30, 1997, and the Federal final rules published in the **Federal Register** on December 8, 1997, May 26, 1998, June 8, 1998, and on June 19, 1998 with certain exceptions described in section H in the Supplementary Information section of this document. EPA has determined that its hazardous waste program revisions satisfy all of the requirements necessary to qualify for Final authorization, and is authorizing the state program revision through this immediate final action. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial action and does not anticipate adverse comments. However, in the proposed rules section of this **Federal Register**, EPA is publishing a separate document that will serve as a proposal to authorize the revision should the Agency receive adverse comment. If EPA receives comments that oppose this action or portion(s) thereof, we will publish a document in the **Federal Register** withdrawing this rule or portion(s) thereof before it takes effect and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes. Unless EPA receives adverse written comments during the review and comment period, the decision to authorize West Virginia's hazardous waste program revision will take effect as provided below.

DATES: This Final authorization for West Virginia will become effective without further notice on July 10, 2000, unless EPA receives adverse comments by June 9, 2000. Once again if EPA should receive such comments on its decision, the Agency will publish a timely withdrawal informing the public that this rule will not take effect.

ADDRESSES: Send written comments to Sharon McCauley, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–3376. EPA must receive your comments by June 9, 2000. Copies of the West Virginia program revision application and the materials which EPA used in evaluating the revision are available for inspection and copying from 8 a.m. to 4:30 p.m., Monday through Friday at the following addresses: West Virginia Division of Environmental Protection, Office of Waste Management, 1356 Hansford Street, Charleston, WV 25301–1401, Phone number: 304–558–4253 and EPA Region III, Library, 2nd Floor, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–5254.

FOR FURTHER INFORMATION CONTACT: Sharon McCauley, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–3376.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), provides for authorization of State hazardous waste programs under Subtitle C. Under RCRA section 3006, EPA may authorize a State to administer and enforce the RCRA hazardous waste