408. 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 FIFRA section 18 petition under FFDCA section 408, 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).

V. 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: December 19, 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), 346(a) and 371.

§ 180.431 [Amended].

2. In § 180.431, amend the table in paragraph (b) by revising the ''Expiration/revocation date'' ''7/31/01'' for the commodity ''Cranberries'' to read ''12/31/03''.

[FR Doc. 01–25 Filed 1–2–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301085; FRL–6757–9]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of myclobutanil in or on sugarbeet roots, tops and by-products. This action is in response to the declaration of a crisis emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarbeets in the state of Idaho. This regulation establishes a maximum permissible level for residues of myclobutanil in these food commodities. The tolerances will expire and are revoked on December 31, 2002.

DATES: This regulation is effective January 3, 2001. Objections and requests for hearings, identified by docket control number OPP–301085, must be received by EPA on or before March 5, 2001.

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 VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301085 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	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,'' ''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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301085. 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the fungicide myclobutanil in or on beet, sugar, roots at 0.05 part per million (ppm); beet, sugar, tops at 1.0 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 1.0 ppm; and beet, sugar, refined sugar at 0.70 ppm. These tolerances will expire and are revoked on December 31, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) 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. . . .''

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

III. Emergency Exemption for Myclobutanil on Sugarbeets and FFDCA Tolerances

EPA has authorized under FIFRA section 18 the use of myclobutanil on sugarbeets for control of powdery mildew in Idaho. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of myclobutanil in or on sugar beets and sugar beet byproducts. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sugar beets and the sugar beet byproducts after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether myclobutanil meets EPA's registration requirements for use on sugarbeets or whether permanent tolerances for this use would be

appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of myclobutanil by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Idaho to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for myclobutanil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), 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 myclobutanil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of myclobutanil in or on beet, sugar, roots at 0.05 ppm; beet, sugar, tops at 1.0 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 1.0 ppm; and beet, sugar, refined sugar at 0.70 ppm.

EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. 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 endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (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 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 $1x10^{-6}$or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for myclobutanil used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MYCLOBUTANIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF[1] and LOC for Risk Assessment	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[2] 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 (1–7 days) (Occupational/Residential)	dermal study NOAEL= 100 mg/kg/day	Acceptable MOE = 100 (Occupational) Acceptable 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.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MYCLOBUTANIL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF[1] and LOC for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (1 week–several months) (Occupational/Residential)	oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 50%)	Acceptable MOE = 100 (Occupational) Acceptable 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 - lifetime) (Occupational/Residential)	oral study NOAEL= 2.49 mg/kg/day (dermal absorption rate = 50%)	Acceptable MOE = 100 (Occupational) Acceptable 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 (1–7 days) (Occupational/Residential)	oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	Acceptable MOE = 100 (Occupational) Acceptable 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 - several months) (Occupational/Residential)	oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	Acceptable MOE = 100 (Occupational) Acceptable 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 Inhalation (several months - lifetime) (Occupational/Residential)	oral study NOAEL= 2.49 mg/kg/day (inhalation absorption rate = 100%)	Acceptable MOE = 100 (Occupational) Acceptable 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.
[2.] The HIARC document (dated 9/2/99) table incorrectly lists this as rat.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.443) for the combined residues of myclobutanil, [α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] plus its alcohol metabolite [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] (free and bound), in or on a variety of raw agricultural commodities at levels ranging from 25.0 ppm in raisin waste to 0.02 ppm in cottonseed. Tolerances have also been established (40 CFR 180.443(b)) for the combined residues of myclobutanil plus its alcohol metabolite (free and bound) and diol metabolite [α-(4-chlorophenyl)-α-(3,4-dihydroxybutyl)-1H-1,2,4-triazole-1-propanenitrile], in meat, milk, poultry and eggs, at levels ranging from 0.02 ppm 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 one 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: The acute analysis was performed for females 13–50 years old using published and proposed tolerance level residues and 100% CT for all commodities. Therefore, the acute risk was analyzed at the 95th percentile. The aPAD for females 13–50 years old is 0.6 mg/kg/day. For acute dietary risk, EPA's level of concern is >100% aPAD. No acute dietary exposure analysis was performed for the general U.S. population, including infants and children, because no endpoint was chosen for these population subgroups.

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 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: 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. *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 PCT information as follows: apples at 40%, apricots at 15%, cherries at 40%, grapes at 45%, nectarines at 20%, peaches at 10%, plums at 15% and cotton at 1%.

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 of the fact that 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 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 exposures are estimated to be 115 parts per billion (ppb) for surface water and 2 ppb for ground water. The EECs for chronic exposures are estimated to be 92 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 μg/cm² (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).

C. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the 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 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.

2. *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.

3. *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:

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

ii. 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;

iii. 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 data base; and

iv. 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.

D. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and groundwater are less than the calculated DWLOCs, 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. 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, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—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	18000

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 18% of the cPAD for the U.S. population, 50% of the cPAD for infants <1 year old and 54% of the cPAD for children 1 to 6 years old. There are no residential uses for myclobutanil that result in chronic residential exposure to myclobutanil. In addition, despite the potential for chronic 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, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—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	18	31	2	720
All infants (1 year old)	0.025	50	31	2	130
Children 1 to 6 years	0.025	54	31	2	120
Children 7 to 12 years	0.025	27	31	2	180

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). Myclobutanil is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for myclobutanil.

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 300 for infants and children. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of myclobutanil in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—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)	Inter-mediate-Term DWLOC (ppb)
U.S. Population	650	100	31	2	3000
Infants and Children	300	100	31	2	670

5. *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.

6. *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.

V. 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 GLC using a nitrogen/phosphorus detector for myclobutanil and an electron capture detector (Ni63) 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, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for myclobutanil on sugar beets. Thus, harmonization is not an issue for this section 18.

C. Conditions

For permanent tolerances and a section 3 registration, the petitioner must submit adequate residue field trial data. A final decision on the appropriate tolerance levels will be withheld pending submission of the requisite residue data. The submitted residue data support a 28–day PHI. No processed commodity data were submitted in support of the emergency exemption request. Therefore, in order to represent the worst case scenario, maximum theoretical concentration factors were used to determine the appropriate tolerances on sugar beet processed commodities. Adequate processed commodity data must be submitted for registration and permanent tolerances. Once these data are submitted and reviewed, EPA will determine if tolerances on sugar beet processed commodities are needed.

VI. Conclusion

Therefore, the tolerance is established for combined residues of myclobutanil, in or on beet, sugar, roots at 0.05 ppm; beet, sugar, tops at 1.0 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, molasses at 1.0 ppm; and beet, sugar, refined sugar at 0.70 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA 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–301085 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 March 5, 2001.

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 VII.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 the docket control number OPP–301085, 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).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. 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 FIFRA section 18 exemption under FFDCA section 408, 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).

IX. 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: December 19, 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), 346(a) and 371.

2. Section 180.443 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.443 Myclobutanil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* *	* *	*
Beet, sugar, dried pulp	1.0	12/31/02
Beet, sugar, molasses	1.0	12/31/02
Beet, sugar, refined sugar	0.70	12/31/02
Beet, sugar, roots	0.05	12/31/02
Beet, sugar, tops	1.0	12/31/02
* *	* *	*

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