FR 38025) is withdrawn as of August 24, 2005.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0225; FRL–7731–2]

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of myclobutanil in or on soybeans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of myclobutanil in this food commodity. The tolerance will expire and is revoked on December 31, 2009.

DATES: This regulation is effective August 24, 2005. Objections and requests for hearings must be received on or before October 24, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0225. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *Sec-18-Mailbox@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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

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

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile and its alcohol metabolite (alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound), in or on soybean at 0.05 parts per million (ppm). EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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

III. Emergency Exemption for Myclobutanil on Soybeans and FFDCA Tolerances

The States of Minnesota and South Dakota, as lead state agencies in what is essentially a ''national'' section 18 request for all soybean growing states, have petitioned the Agency requesting an emergency exemption for myclobutanil to control soybean rust

under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On November 10, 2004, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) confirmed the presence of *Phakopsora pachyrhizi*, the pathogen that causes soybean rust, on soybean leaf samples taken from two plots associated with a Louisiana State University research farm. Soybean rust has been designated as a biosecurity threat and therefore it is important that control measures be available for the disease. EPA has authorized under FIFRA section 18 the use of myclobutanil on soybeans for control of soybean rust in Minnesota, South Dakota, and all the other states that have requested an exemption for this use. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of myclobutanil in or on soybeans. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybeans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether myclobutanil meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of myclobutanil by a state for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any state other than those which have been granted exemptions as part of the soybean rust section 18 to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for 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 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of myclobutanil and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of myclobutanil in or on soybeans at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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

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

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

Exposure/Scenario	Dose Used in Risk/Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor*	Study and Toxicological Effects
Acute dietary (Females 13–50)	NOAEL = 60 milligrams/kilogram/day (mg/kg/day) UF =100 Acute RfD = 0.6 mg/kg/day	FQPA SF = 1X aPAD = acute RfD = 0.6 mg/kg/day	Developmental toxicity study - Rats LOAEL = 200 mg/kg/day based on increased resorptions, decreased litter size
Chronic dietary (All populations)	NOAEL= 2.49 mg/kg/day UF = 100 Chronic RfD = 0.025 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD = 0.025 mg/kg/day	Chronic toxicity/Oncogenicity study - Rats LOAEL = 10 mg/kg/day based on decreased testicular weights and increased testicular atrophy
Short-term (1–30 days) Dermal	NOAEL = 100 mg ai/kg/day	Residential MOE = 100	28–day Dermal toxicity - Rats There were no signs of toxicity at the high dose of 100 mg/kg a.i.
Intermediate-term (1–6 months) Dermal	Oral NOAEL = 10 mg ai/kg/day	Residential MOE = 100	2–Generation reproduction toxicity - Rats LOAEL = 50 mg/kg bw/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 (> 6 months)	Oral NOAEL = 2.49 mg/kg/day	Residential MOE = 100	Chronic toxicity/Carcinogenicity - Rats LOAEL = 10 mg/kg/day based on decreased testicular weights and increased testicular atrophy
Short-term (1–30 Days) Inhalation	Oral NOAEL = 10 mg/kg/day	Residential MOE = 100	2–Generation reproduction toxicity study - Rats LOAEL = 50 mg/kg bw/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 (1–6 months) Inhalation	Oral NOAEL = 10 mg/kg/day	Residential MOE = 100	2–Generation reproduction toxicity study - Rats LOAEL = 50 mg/kg bw/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 (> 6 months)	Oral NOAEL = 2.49 mg/kg/day	Residential MOE = 100	Chronic toxicity/Carcinogenicity - Rats LOAEL = 10 mg/kg/day based on decreased testicular weights and increased testicular atrophy
Cancer	Group E- likely not a human carcinogen		

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

B. Exposure Assessment

1. *Dietary exposure from food and drinking water.* Tolerances are established for combined residues of the fungicide myclobutanil alpha-butyl–alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile and its alcohol metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound), ranging from 0.02 ppm on cotton seed and eggs to 25 ppm on grape raisin waste. Time-limited tolerances and tolerances for inadvertent residues have also been established.

In conducting the acute and chronic dietary risk assessments, EPA used the Dietary Exposure Evaluation Model (DEEM™) software. Modeled estimates of drinking water concentrations were directly entered into the exposure model to assess the contribution from drinking water. 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 DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute analysis is a conservative Tier 1 assessment based on tolerance-level residues and the assumption of 100% crop treated (PCT) for established and proposed myclobutanil tolerances. DEEM™ default processing factors from DEEM™ (Version 7.76) were used for all processed commodities that do not have individual tolerances. Aggregate acute food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The highest estimate for acute water exposure, 333 parts per billion (ppb), was used in the analysis.

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

1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The chronic analysis is based on partially refined Tier 3 assumptions in that it incorporates estimates of average PCT for some crops, as well as Pesticide Data Program (PDP) monitoring data from apple juice, bananas (not plantains) and milk. The following average PCT information was used: Apples, 40%; apricots, 15%; cherries, 40%; grapes, 45%; nectarines, 20%; peaches, 10%; plums, 15%; and cotton, 1%. One hundred PCT was assumed for all other commodities. DEEM™ default processing factors from DEEM™ (Version 7.76) were used for all processed commodities that do not have individual tolerances. Aggregate chronic food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The highest estimate for chronic water exposure, 86 ppb, was used in the analysis.

iii. *Cancer*. The Agency has classified myclobutanil as a ''Group E - not likely human carcinogen'' and, therefore, quantification of human cancer risk is not required.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Apples, 40%; apricots, 15%; cherries, 40%; grapes, 45%; nectarines, 20%; peaches, 10%; plums, 15%; and cotton, 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 First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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.

Based on the FIRST and SCI-GROW models, the estimated environmental concentrations (EECs) of myclobutanil for acute exposures are estimated to be 333 ppb for surface water and 3.2 ppb for ground water. The EECs for chronic exposures are estimated to be 86 ppb for surface water and 3.2 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Myclobutanil is present in numerous end-use products, including those registered for use on turf, roses, flowers, shrubs and trees. Soluble concentrate may be applied with hose-end or trigger bottle sprayers. Small scale lawn

application has the greatest potential for homeowner exposures. Short- and intermediate-term exposures are expected for residential handlers. The Agency has determined that a 50% dermal absorption factor should be applied for intermediate-term assessments. A dermal absorption factor is not required for short-term assessments because the NOAEL used is based upon a 28–day dermal study.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to myclobutanil and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

However, the Agency does have concern about potential toxicity to 1,2,4-triazole and two conjugates, triazolylalanine and triazolyl acetic acid, metabolites common to most of the triazole fungicides. To support the extension of existing parent triazole-derivative fungicide tolerances, EPA conducted an interim human health assessment for aggregate exposure to 1,2,4-triazole. The exposure and risk estimates presented in this assessment are overestimates of actual likely exposures and therefore, should be considered to be highly conservative. Based on this assessment EPA concluded that for all exposure durations and population subgroups, aggregate exposures to 1,2,4-triazole are not expected to exceed EPA's LOC. This assessment is presented in the April 22, 2005 **Federal Register** (70 FR 20821) (FRL–7702–4) notice for another triazole fungicide, tetraconazole. This assessment should be considered interim due to the ongoing series of studies being conducted by the U.S. Triazole Task Force (USTTF). Those studies are designed to provide the Agency with more complete toxicological and residue information for free triazole. Upon completion of the review of these data, EPA will prepare a more sophisticated assessment based on the revised toxicological and exposure data bases.

C. Safety Factor for Infants and Children

Section 408 of the FFDCA 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

As outlined in Table 1 (above), 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. In a range of laboratory studies to indicate concerns regarding developmental toxicity, reproductive toxicity and prenatal and postnatal sensitivity, EPA's analysis reconfirmed previous findings, that an additional FQPA safety factor is not necessary for myclobutanil. Existing default safety factors provide adequate protection for public health, including for infants and children.

D. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the chemical in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA will reassess the potential impacts of myclobutanil on drinking water as a part of the aggregate risk assessment process.

More recently the Agency has begun using another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This can provide a more realistic estimate of exposure because actual body weights and water consumption from the CSFII can often be used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. Combining screening level estimates of pesticide residues in drinking water from drinking water models with what may be more realistic values for residues in food is not ideal. Once screening level values are combined with more realistic values it is easy to lose sight of the fact that aggregate exposure estimate is based on a mixture of very conservative and more realistic estimates. Nonetheless, this

concern with mixing screening level and more realistic values is outweighed where the Agency is able to incorporate information on actual body weights and water consumption into the aggregate exposure calculation. This risk assessment for myclobutanil was conducted using this approach.

1. *Acute risk*. The acute dietary endpoint for females in the 13 to 50 year age group is based on the NOAEL for a developmental toxicity in rabbits which manifested as increases in resorptions, decreases in litter size. This endpoint is considered appropriate for females of childbearing age (13–50 years old) since the effects could occur due to a single *in utero* exposure. There were no appropriate toxicological effects for the general population attributable to a single exposure (dose) observed in oral toxicity studies including the maternal effects in the developmental toxicity studies in rats and rabbits. Therefore, an acute dose and an endpoint were not selected for the general population for this risk assessment.

Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to myclobutanil will occupy 4% of the aPAD for the population subgroup of interest, females 13–49 years old.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO MYCLOBUTANIL

Population Subgroup	aPAD (mg/kg)	% aPAD/(Food + Water)
Females (13–49 years old)	0.6	4%

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to myclobutanil from food and water will utilize 21% of the cPAD for the U.S. population, 41% of the cPAD for all infants < 1 year old, and 45% of the cPAD for children 1–2 years old. Based the use pattern, chronic residential exposure to residues of myclobutanil is not expected.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO MYCLOBUTANIL

Population Subgroup	cPAD/(mg/kg/day)	% cPAD
General U.S. population	0.025	21%
All Infants (< 1 year old)	0.025	41%
Children (1–2 years old)	0.025	45%
Children (3–5 years old)	0.025	38%
Children (6–12 years old)	0.025	25%
Youth (13–19 years old)	0.025	16%
Adults (20–49 years old)	0.025	18%
Adults (50+ years old)	0.025	19%
Females (13–49 years old)	0.025	18%

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).

Myclobutanil is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for myclobutanil. For short-term aggregate exposure risk assessment, even though there was no systemic toxicity in a dermal study, by combining dermal with oral and inhalation exposures would provide the most conservative risk assessment approach. Since all the acceptable short-term MOEs are 100 but the NOAELs vary (short-term dermal NOAEL is 100 mg/kg/day, all others are 10 mg/kg/day), the reciprocal equation approach will be used to calculate aggregate short-term risk estimates. The aggregate short-term exposure estimates are below the Agency's LOC (MOEs < 100).

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO MYCLOBUTANIL

Population Subgroup	Target MOE	Food + Water			Dermal MOE	Oral MOE	Aggregate MOE[3]
		NOAEL[1] (mg/kg/day)	Average Food + Water Exposure (mg/kg/day)	MOE[2]			
Children (1–2 years old)	100	10	0.011230	890	830	140	110
U.S. population	100	10	0.005234	1,900	1,400	N/A	800

1 Short-term Oral NOAEL
2 MOE = NOAEL/Exposure
3 Aggregate MOE = [1÷ ((1/MOE Food + Water) + (1/MOE Dermal) + (1/MOE Oral))]

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. For myclobutanil intermediate-term aggregate exposure risk assessment, oral, dermal and inhalation exposures can be combined because dermal and inhalation exposures can be expressed

as oral equivalent doses. The aggregate intermediate-term exposure estimates for myclobutanil do not include inhalation exposure, as there is no associated scenario.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 330 for children 1–2 years old and 620 for the general U.S. population. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water and residential uses.

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

Population Subgroup	NOAEL (mg/kg/day)	Max allowable exposure[1] (mg/kg/day)	Average Food + Water Exposure (mg/kg/day)	Dermal Exposure (mg/kg/day)	Oral Exposure (mg/kg/day)	Residential Exposure (mg/kg/day)[2]	Aggregate MOE[3]
Children (1–2 years old)	10	0.1	0.011230	0.018	0.0013	0.0193	330
U.S. population	10	0.1	0.005234	0.011	N/A	0.011	620

1 Maximum Exposure (mg/kg/day) = NOAEL/Target MOE of 100.
2 Residential Exposure = The combined dermal and incidental oral ingestion for infants and dermal only for adults.
3 Aggregate MOE = [NOAEL ÷ (Avg Food & Water Exposure + Residential Exposure)]

5. *Aggregate cancer risk for U.S. population*. The Agency has classified myclobutanil as a ''Group E - not likely human carcinogen'' and, therefore, quantification of human cancer risk is not required.

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

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRLs) for myclobutanil on soybeans. Therefore, there are no international harmonization issues associated with this action.

VI. Conclusion

Therefore, the tolerance is established for combined residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile and its alcohol metabolite (alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound), in or on soybeans at 0.05 ppm.

VII. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0225 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 24, 2005.

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

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

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2005–0225, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*.

Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 12, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

n Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

n 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

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

§ 180.443 Myclobutanil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Soybean	0.05	12/31/09

* * * * *

[FR Doc. 05–16805 Filed 8–23–05; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041126333–5040–02; I.D. 081805B]

Fisheries of the Economic Exclusive Zone Off Alaska; Shallow-Water Species Fishery by Vessels Using Trawl Gear in the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for species that comprise the shallow-water species fishery by vessels using trawl gear in the Gulf of Alaska (GOA). This action is necessary because the third seasonal apportionment of the 2005 Pacific halibut bycatch allowance specified for the shallow-water species fishery in the GOA has been reached.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), August 19, 2005, through 1200 hrs, A.l.t., September 1, 2005.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The third seasonal apportionment of the 2005 Pacific halibut bycatch allowance specified for the shallow-water species fishery in the GOA is 200 metric tons as established by the 2005 and 2006 harvest specifications for groundfish of the GOA (70 FR 8958, February 24, 2005), for the period 1200 hrs, A.l.t., July 5, 2005, through 1200 hrs, A.l.t., September 1, 2005.

In accordance with § 679.21(d)(7)(i), the Administrator, Alaska Region, NMFS, has determined that the third seasonal apportionment of the 2005 Pacific halibut bycatch allowance specified for the trawl shallow-water species fishery in the GOA has been reached. Consequently, NMFS is prohibiting directed fishing for the shallow-water species fishery by vessels using trawl gear in the GOA. The species and species groups that comprise the shallow-water species fishery are pollock, Pacific cod, shallow-water flatfish, flathead sole, Atka mackerel, skates and ''other species.''

This closure does not apply to fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA open to directed fishing for pollock.

After the effective date of this closure the maximum retainable amounts at §§ 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of the shallow-water species fishery by vessels using trawl gear in the GOA.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 18, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–16839 Filed 8–19–05; 2:24 pm]

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