

**§ 1280.2 What property is under the control of the Archivist of the United States?**

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(d) *The National Archives Southwest Region.* The National Archives Southeast Region in Morrow, Georgia as specified in 36 CFR 1253.7 (e).

(e) *The Federal Records Centers.* The Federal Records Centers in Ellenwood, Georgia, and Riverside, California, as specified in 36 CFR 1253.6 (d) and (l), respectively.

(f) *Additional Facilities.* As other properties come under the control of the Archivist of the United States, they will be listed in these regulations as soon as practicable.

**§§ 1280.4, 1280.6 and 1280.8 [Redesignated as §§ 1280.6, 1280.8 and 1280.4]**

■ 4. In Subpart A, redesignate §§ 1280.4, 1280.6 and 1280.8 as §§ 1280.6, 1280.8 and 1280.4, respectively.

■ 5. Revise newly designated § 1280.4 to read as follows:

**§ 1280.4 What items are subject to inspection by NARA?**

NARA may, at its discretion, inspect the personal property in the possession of any NARA contractor, employee, student intern, visitor, volunteer, or other person arriving on, working at, visiting, or departing from NARA property.

Dated: December 13, 2006.

**Allen Weinstein,**

*Archivist of the United States.*

[FR Doc. E6-21682 Filed 12-19-06; 8:45 am]

BILLING CODE 7515-01-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0282; FRL-8105-1]

**Myclobutanil; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of myclobutanil in or on hops, soybean seed, soybean forage, soybean hay, aspirated grain fractions, and soybean refined oil. Interregional Research Project #4 (IR-4) requested the tolerance for hops and Dow AgroSciences requested the tolerances for the soybean commodities under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective December 20, 2006. Objections and requests for hearings must be received on or before February 20, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0282. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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:** Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

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

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0282 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 February 20, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0282, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of April 12, 2006 (71 FR 18740) (FRL-7773-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E6265) by Interregional Research Project No. 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.443 be amended by 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 hop, dried cones at 10 parts per million (ppm). That notice included a summary of the petition prepared by Dow AgroSciences, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of August 23, 2006 (71 FR 49448) (FRL-8073-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6997) by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.443 be amended by establishing tolerances 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, aspirated grain fractions at 1.1 ppm; soybean, forage at 5.0 ppm; soybean, hay at 13.0 ppm; soybean, hulls at 0.06 ppm; soybean, meal at 0.03 ppm; soybean, oil at 0.1 ppm; and soybean, seed at 0.05 ppm. That notice included a summary

of the petition prepared by Dow AgroSciences, the registrant. There were no comments received in response to the notice of filing.

Upon completing review of the current myclobutanil database, the Agency concluded that the appropriate tolerance levels for myclobutanil residues in or on pending crops should be established as follows: Hop, dried cones at 10 ppm; soybean, seed at 0.25 ppm; soybean, forage at 3.5 ppm; soybean, hay at 15 ppm; aspirated grain fractions at 35 ppm; and soybean, refined oil at 0.40 ppm. In addition, the proposed tolerances for soybean, hulls and soybean, meal were withdrawn because based on available processing data, tolerances for these commodities are not needed.

EPA is also deleting several established tolerances in 40 CFR 180.443(b) that are no longer needed as a result of this action. The tolerance deletions under 40 CFR 180.443(b) are time-limited tolerances established under section 18 emergency exemptions that are superseded by the establishment of general tolerances for myclobutanil and its metabolites under 40 CFR 180.443(a).

The revisions to 40 CFR 180.443(b) are as follows:

Delete the time-limited tolerance for hop, dried cone at 5.0 ppm. A tolerance for hop, dried cones at 10 ppm is established by this action under 40 CFR 180.443(a).

Delete the time-limited tolerance for soybean at 0.05 ppm. A tolerance for soybean, seed at 0.25 ppm is established by this action under 40 CFR 180.443(a).

Section 408(b)(2)(A)(i) of 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 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 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...."

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 <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of 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 hop, dried cones at 10 ppm; soybean, seed at 0.25 ppm; soybean, forage at 3.5 ppm; soybean, hay at 15 ppm; grain, aspirated fractions at 35 ppm; and soybean, refined oil at 0.40 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by myclobutanil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.epa.gov/fedrgstr/EPA-PEST/2000/May/Day-10/p11571.htm> (**Federal Register** of May 10, 2000 (65 FR 29963) (FRL-6555-5).

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the 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.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for myclobutanil used for human risk assessment can be found at [www.regulations.gov](http://www.regulations.gov) in document 0002 (pages 6 and 7) in docket ID number EPA-HQ-OPP-2006-0282. To locate this information on the [Regulations.gov](http://www.regulations.gov) website follow these steps:

- Select "Advanced Search", then "Docket Search"
- In the "Keyword" field type the chemical name or insert the applicable "Docket ID number." (example: EPA-HQ-OPP-2005-9999)
- Click the "Submit" button.

Follow the instructions on the [regulations.gov](http://www.regulations.gov) web site to view the index for the docket and access available documents.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.443) for the combined residues of myclobutanil, in or on a variety of raw agricultural commodities. Tolerances have also been established for combined residues of myclobutanil in or on milk, egg, and fat, liver, meat, and meat byproducts of cattle, goat, hog, horse, and sheep as well as fat, meat, and meat byproducts of poultry. Risk assessments were conducted by EPA to assess dietary exposures from myclobutanil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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.

An acute dietary exposure assessment was performed for females 13-49 years old (no endpoint was identified for the general U.S. population or any other population subgroup). In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-

FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994-1996 and 1998 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: Tolerance-level residues and 100 percent crop treated (PCT) information for all registered and proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data 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 following assumptions were made for the chronic exposure assessments: A partially refined, chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups using USDA Pesticide Data Program (PDP) monitoring data for apple juice, bananas (not plantains) and milk and assuming all other commodities covered by registered and proposed tolerances have residues at the appropriate tolerance value. Average PCT information was used for apple (except juice), apricots, asparagus, blackberry, cantaloupe, cherry, cucumber, grape, nectarine, peach, plum, pumpkin, raspberry, squash, strawberry, tomato, and watermelon; 100 PCT was assumed for all other registered and proposed uses.

iii. *Cancer.* The Agency has classified myclobutanil as Group E - not likely to be a human carcinogen. Myclobutanil was determined to be not carcinogenic in two acceptable animal studies. Therefore, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) of 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 FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

40% of apples (except juice), 25% of apricots, 5% of asparagus, 15% of blackberry, 10% of cantaloupe, 35% of cherry, 1% of cucumber, 25% of grape, 15% of nectarine, 10% of peach, 10% of plum, 15% of pumpkin, 25% of raspberry, 10% of squash, 35% of strawberry, 5% of tomato, and 5% of watermelon.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum.

EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed in Unit III.C.iv. 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. 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.

3. *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. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the PRZM/EXAMS and SCI-GROW models, the estimated environmental concentrations (EECs) of myclobutanil for acute exposures are estimated to be 15.3 parts per billion (ppb) for surface water and 0.35 ppb for ground water. The EECs for chronic exposures are estimated to be 8.5 ppb for surface water and 0.35 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). The estimates were calculated using the application rate for hops, which has the highest use rate among all existing and proposed uses. For acute dietary risk assessment the 1-in 10-year peak acute of 15.3 ppb was used to assess the contribution to drinking water and for chronic dietary risk assessment the 1-in 10-year estimated annual mean of 8.5 ppb was used to assess the contribution to drinking water.

4. *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 currently registered for use on the following residential non-dietary sites: Turf, ornamentals, and home garden uses on fruit trees, nut trees, berries, mint and vegetables. The risk assessment was conducted using the following residential exposure assumptions:

The homeowner use with the greatest potential for exposure is small-scale

lawn application. Since myclobutanil is applied at 7- to 14-day intervals, only short-term exposure is expected for the residential handler. Short- and intermediate-term residential post-application exposures are also expected.

The current use patterns and labeling indicate that a variety of application equipment could be used by the homeowner to apply myclobutanil to ornamental plants, shrubs, fruit trees, home garden vegetables and lawns. Therefore, the following scenarios were assessed:

- i. Aerosol Spray Can Application to Ornamentals and Fruit Trees
- ii. Hose End Sprayer Application to Ornamentals and Fruit Trees
- iii. Low-pressure (LP) Handwand Application to Ornamentals
- iv. LP Handwand Application to Vegetables
- v. Ready to use (RTU) Sprayer Application to Vegetables
- vi. Hose End Sprayer Application to Vegetables
- vii. Hose End Sprayer - Mix Your Own - Application to Turf
- viii. Hose End Sprayer - Ready to Use - Application to Turf
- ix. Belly Grinder Application to Turf
- x. Broadcast Spreader Application to Turf

Unit exposure data were either taken from Pesticide Handler's Exposure Database (PHED) or from the home garden and turf application studies that were sponsored by the Outdoor Residential Exposure Task Force (ORETF).

Home garden post-application exposures can occur when home gardeners perform tasks such as weeding, pruning or hand harvesting following application of myclobutanil. In order to address these risks, the post-application exposure to home gardens and orchard scenarios were assessed based upon the Residential standard operating procedures (SOP) 3.0 for Garden Plants and SOP 4.0 for Trees.

Two dislodgeable foliar residue (DFR) studies on grapes in California were used to assess the home garden exposures. The studies were performed using airblast sprayers while the proposed home garden applications would be made with LP handwand or hose end sprayers. Based upon experience with other fungicides, however, it is anticipated that DFRs resulting from handwand applications would be similar to DFRs from airblast applications. The initial DFR was assumed to be 23% of the application rate.

“Pick your own” exposures can occur at commercially operated “pick your own” strawberry farms and orchards

where myclobutanil has been applied. To address these risks, post-application exposure for pick your own strawberries and tree fruit were assessed based upon the Residential SOP 15.0 for “pick your own” strawberries. The DFR data that were used for the home gardener post-application risks were also used to assess “pick your own” exposures. The exposure estimates used for pick your own exposures are considered conservative because that scenario is based upon a screening-level transfer coefficient (TC) and a dermal absorption factor of 50%.

The following scenarios were assessed for residential turf post-application exposures and risks:

- a. Toddlers Playing on Treated Turf
- b. Adults Performing Yard work on Treated Turf
- c. Adults Playing Golf on Treated Turf

A turf transferable residue (TTR) study was used to assess the turf exposures. The field portion of this study was in North Carolina and California. The initial TTR for dermal exposures was assumed to be 2.4% of the application rate and was based upon an average of the days after treatment (DAT) of 0 and DAT of 3 for the California site. The maximum application rate for turf of 0.62-0.68 pounds active ingredient per acre (lb ai/A) was used to assess the turf exposures.

Additional information on residential exposure assumptions can be found at <http://www.regulations.gov> (Docket ID number EPA-HQ-OPP-2006-0282-0005, pages 13 through 17).

5. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA 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.”

Myclobutanil is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some

induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Myclobutanil is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including myclobutanil, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov> (Docket ID number EPA-HQ-OPP-2005-0497).

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of 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 database on toxicity and exposure unless EPA determines based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no indication of quantitative or qualitative increased susceptibility in rats or rabbits from *in utero* and/or postnatal exposure to myclobutanil. In the rat developmental toxicity study, maternal toxicity, which included rough hair coat and salivation, alopecia, desquamation and red exudate around mouth occurs at the same dose level as increases in incidences of 14th rudimentary and 7th cervical ribs in the fetuses. The maternal and developmental toxicity NOAELs in the rat developmental toxicity study were 93.8 mg/kg/day. EPA concludes that there is no evidence qualitative susceptibility in rat developmental toxicity study since the fetal variations (14th rudimentary ribs and 7th cervical ribs) are normal occurrence control animals that occurred in the presence severe maternal toxicity (red exudate around mouth and salivation). In the rabbit developmental toxicity study there is reduced body weight and body weight gain during the dosing period, clinical signs of toxicity such as bloody urine and bloody urogenital or anal area and a possible increase in abortions (blood and/or aborted material in the cage pan) in the does at the same dose level as developmental toxicity manifested as increased resorptions, decreased litter size and decreased viability index. The maternal and developmental toxicity NOAELs in the rabbit developmental toxicity study were 93.8 mg/kg/day. EPA concludes that there is no evidence qualitative susceptibility in rabbit developmental toxicity study since the fetal effects (resorptions, decreased litter size and viability) occurred in the presence equally severe maternal toxicity (abortions, bloody urine and bloody urogenital or anal area). The maternal NOAEL in the 2-generation reproduction study was 50 ppm (2.5 mg/kg/day) based on hepatocellular hypertrophy and increased in liver weight seen at 200 ppm (10 mg/kg/day; LOAEL). The offspring toxicity NOAEL was 200 ppm (10 mg/kg/day) based on decreased in pup body weight gain

during lactation seen at 1,000 ppm (50 mg/kg/day; LOAEL). The reproductive toxicity NOAEL was 200 ppm (10 mg/kg/day) based on increased incidences in the number of still born pups and atrophy of the testes, epididymides and prostate observed at 1,000 ppm (50 mg/kg/day; LOAEL). EPA concludes that there is no evidence on increased susceptibility (qualitative or quantitative) in the 2-generation reproduction study in rats because the offspring and reproductive toxicity were observed at a higher dose than the dose that caused maternal toxicity.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. The decision is based on the following findings:

- i. There is a complete toxicity data base for myclobutanil.
- ii. There was no evidence of increased susceptibility in the developmental toxicity studies with rats and rabbits.
- 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 database.
- 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.
- v. The acute dietary food exposure assessment (females 13-49 years old only) utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- vi. The chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues; USDA Pesticide Data Program (PDP) monitoring data for apple juice, bananas (not plantains) and milk; average PCT data for some commodities and 100 PCT information for all other registered and proposed uses. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.
- vii. The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters, which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- viii. The residential handler assessment is based upon the residential SOPs and utilized unit exposure data

from the ORETF and the PHED. The residential post-application assessment is based upon chemical-specific turf transferable residue (TTR) data and DFR data. The chemical-specific study data as well as the surrogate study data used are reliable and also are not expected to underestimate risk to adults as well as to children. In a few cases where chemical-specific data were not available, the SOPs were used alone. The residential SOPs are based upon reasonable "worst-case" assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to myclobutanil.

#### E. Aggregate Risks and Determination of Safety

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to myclobutanil will occupy 2.4% of the acute Adjusted Population Dose (aPAD) for females 13 years and older. No endpoint was identified for the general U.S. population or any other population subgroup. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

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 10% of the chronic Population Adjusted Dose (cPAD) for the U.S. population, 17% of the cPAD for all infants less than 1 year old, and 25% of the cPAD for children 1-2 years old, the subpopulation at greatest exposure. There are no residential uses for myclobutanil that result in chronic residential exposure. Therefore, chronic residential exposure to residues of myclobutanil is not expected. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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). The short-term aggregate risk assessments estimate risks likely to result from 1-30 days of exposure to myclobutanil residues in food, drinking water, and residential pesticide uses.

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, water and short-term exposures for myclobutanil.

Using the exposure assumptions described in this unit for short-term

exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate margin of exposures (MOEs) of 180 for the general U.S. population for handler exposures; 300 for the general U.S. population for home gardens post application exposures; 110 for the general U.S. population for "Pick Your Own" fruit tree post application exposures; 130 for the general U.S. population for heavy yard work for turf post application exposures; 1,300 for the general U.S. population for exposures when playing golf and 130 for children 1-2 years old when playing on the lawn post application exposures. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The intermediate-term aggregate risk assessment estimates risks likely to result from 1 to 6 months exposure to myclobutanil residues in food, drinking water, and residential pesticide scenarios.

Myclobutanil is currently registered for uses 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, water, and residential exposures aggregated result in aggregate MOEs of 300 for the general U.S. population for home garden post application exposures; 110 for the general U.S. population for "Pick Your Own" fruit tree post application exposures; 130 for the general U.S. population for heavy yard work for turf post application exposures; 1,300 for the general U.S. population for exposures when playing golf and 130 for children 1-2 years old when playing on the lawn post application exposures. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water, and residential uses. Therefore, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified myclobutanil as Group E - not likely to be a human carcinogen. Myclobutanil was determined to be not carcinogenic in two acceptable animal studies.

Myclobutanil is not expected to pose a cancer risk.

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.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

An adequate enforcement method is available to enforce the proposed tolerances on soybeans and hops. Quantitation is by gas-liquid chromatography (GLC) using a nitrogen/phosphorus (N/P) detector for myclobutanil and an electron capture detector (Ni63) for residues measured as the alcohol metabolite. The EPA has conducted a successful method validation of Method 34S-88-10, and the method has been forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Method Volume II (PAM) Vol. II.

Enforcement methods for the established tolerances on livestock commodities are Methods 34S-88-22, 34S-88-15, 31S-87-02, and 34S-88-21. These methods have been submitted for publication in PAM II.

These methods 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](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no current Codex, Canadian or Mexican maximum residue limits (MRLs) for residues of myclobutanil in/on soybeans. Therefore, harmonization is not an issue. There are no current Canadian or Mexican maximum residue limits (MRLs) for residues of myclobutanil in/on hops. However, there is a Codex MRL of 2 ppm for the parent compound myclobutanil in/on hops, dry. EPA has concluded the submitted residue chemistry data support a tolerance of 10 ppm for residues of myclobutanil and its alcohol metabolite RH-9090 (free and bound). Therefore, harmonization with the Codex MRL is not possible.

#### V. Conclusion

Therefore, tolerances are established for combined residues of 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 hop, dried cones at 10 ppm; soybean, seed at 0.25 ppm; soybean, forage at 3.5 ppm; soybean, hay at 15 ppm; grain, aspirated fractions at 35 ppm; and soybean, refined oil at 0.40 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 petition under section 408(d) of 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 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.

**VII. 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: December 8, 2006.

**Donald R. Stubbs,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.443 is amended:

■ a. In paragraph (a), in the table, by alphabetically adding commodities to read as set forth below; and

■ b. In paragraph (b), in the table, by removing the commodities “Hop, dried cone” and “Soybean”.

**§ 180.443 Myclobutanol; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Grain, aspirated fractions .....	35
Hop, dried cones .....	10
Soybean, forage .....	3.5
Soybean, hay .....	15
Soybean, refined oil .....	0.40
Soybean, seed .....	0.25

\* \* \* \* \*

[FR Doc. E6-21489 Filed 12-19-06; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0532; FRL-8104-6]

**Dimethomorph; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of the fungicide, dimethomorph, (E,Z) 4-[3-(4-