and adding introductory text after the table heading; and revising the entry, ''63.6(e)(3)(i), (e)(3)(iii)–(e)(3)(ix), (f), (g), (h)(1), (h)(2), (h)(4), (h)(5)(i)–(h)(5)(iii), (h)(v)(v), (h)(6)–(h)(9)'' to read as follows:

Table 1 to Subpart QQQQQQ of Part 63–Applicability of General Provisions to Subpart QQQQQQ

As required in § 63.11432, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) as shown in the following table.

Citation	Subject	Applies to subpart QQQQQQ?	Explanation
* * * * *	* * *	* * *	* *
63.6(e)(3)(i), (e)(3)(iii)–(e)(3)(ix), (f), (g), (h)(1), (h)(2), (h)(4), (h)(5)(i)–(h)(5)(iii), (h)(5)(v), (h)(6)–(h)(9).	.....	No	Subpart QQQQQQ does not require a startup, shutdown, and malfunction plan or contain emission or opacity limits.
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[FR Doc. E8–6184 Filed 3–25–08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0107; FRL–8356–2]

Myclobutanil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of myclobutanil and its alcohol metabolite in or on artichoke, globe; black sapote; canistel; cilantro, leaves; leafy greens, subgroup 4A, except spinach; mamey sapote; mango; okra; papaya; sapodilla; star apple; and fruiting vegetable group 8, except tomato. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is also deleting several established myclobutanil tolerances that are no longer needed.

DATES: This regulation is effective March 26, 2008. Objections and requests for hearings must be received on or before May 27, 2008, 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–2007–0107. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility 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*.

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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide 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 EPA's tolerance regulations at 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 FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2007–0107 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 as required by 40 CFR part 178 on or before May 27, 2008.

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 this copy, identified by docket ID number EPA–HQ–OPP–2007–0107, 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 Bldg.), 2777 S. Crystal Dr., 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 Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of April 4, 2007 (72 FR 16352) (FRL–8119–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 3E6562 and 6E7138) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. These petitions requested that 40 CFR 180.443 be amended by establishing tolerances for combined residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and its alcohol metabolite (alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on Black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple at 3.0 parts per million (ppm) (PP 3E6562); and Fruiting vegetables, crop group 8, except tomato at 4.5 ppm; leafy vegetables, crop subgroup 4A, except spinach at 11.0 ppm; globe artichoke at 0.9 ppm; cilantro at 11.0 ppm; and okra at 4.5 ppm in (PP 6E7138). That notice referenced a summary of the petition prepared by Dow Agrosciences LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised some of the commodity definitions and tolerance levels for certain commodities. The reason for these changes is explained in Unit IV.C.

EPA is also deleting several established tolerances in § 180.443(b) that are no longer needed. The tolerance deletions under § 180.443(b) are time-limited tolerances established under section 18 emergency exemptions. The time-limited tolerances for artichoke, globe and pepper are superceded by the establishment of general tolerances for myclobutanil and its alcohol metabolite under § 180.443(a) as a result of this action. The time-limited tolerances for sugar beet dried pulp, sugar molassess, refined sugar, roots, and tops are being deleted since they have expired.

III. Aggregate Risk Assessment and Determination of Safety

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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of myclobutanil and its alcohol metabolite on artichoke, globe at 0.90 ppm; canistel at 3.0 ppm; cilantro, leaves at 9.0 ppm; leafy greens, crop subgroup 4A, except spinach at 9.0 ppm; mango at 3.0 ppm; okra at 4.0 ppm; papaya at 3.0 ppm; sapodilla at 3.0 ppm; sapote, black at 3.0 ppm; sapote, mamey at 3.0 ppm; star apple at 3.0 ppm; and vegetable, fruiting, group 8, except tomato at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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.

Myclobutanil has low acute toxicity with the exception for ocular irritation. In rat subchronic and chronic toxicity studies, the primary target organs are liver and testes. Liver effects, following subchronic exposure, include hypertrophy, hepatocellular necrosis and increased liver weight. Chronic exposure to the rat also results in hepatocellular vacuolization and additional testicular effects, which include bilateral aspermatogenesis, increased incidences of hypospermia and cellular debris in the epididymides and increased incidences of arteritis/periarteritis in the testes. With the exception of testicular effects, subchronic and chronic exposures in the mouse result in a toxicity profile similar to the rat. The mouse, following chronic exposure, has, in addition, increased Kupffer cell pigmentation, periportal punctate vacuolation, and individual cell necrosis of the liver. There is no evidence of carcinogenic potential in either the rat or mouse. In the subchronic dog study, there are hepatocellular hypertrophy, increased relative and absolute liver weight and increased alkaline phosphatase. In the chronic dog study, liver toxicity is similar with the addition of ''ballooned''

hepatocytes and increases in serum glutamic pyruvic transaminase (SGPT) and gamma glutamyl transferase (GGT). Signs of toxicity observed in the rat 28–day dermal studies are limited to dermal irritation. There is no evidence of systemic toxicity in either study. There is no evidence of increased susceptibility in either of the developmental toxicity studies or the reproduction study. There is no concern for mutagenic activity. Myclobutanil was determined to be not carcinogenic in two acceptable animal studies.

Specific information on the studies received and the nature of the adverse 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 are discussed in the final rule published in the **Federal Register** of May 10, 2000 (65 FR 29963) (FRL–6555–5) (*http://www.epa.gov/fedrgstr/EPA-PEST/2000/May/Day-10/p11571.htm*).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for myclobutanil used for human risk assessment can be found at *http://www.regulations.gov* in document Myclobutanil. Human-Health Risk Assessment for Proposed Use on Section 3 Requests for Use on Snap Bean, Mint, Papaya, Gooseberry, Currant, Caneberry, Bell and Non-Bell Pepper, Head and Leaf Lettuce, and Artichoke at page 7 in docket ID number EPA–HQ–OPP–2007–0107.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to myclobutanil, EPA considered exposure under the petitioned-for tolerances as well as all existing myclobutanil tolerances in 40 CFR 180.443. EPA assessed dietary exposures from myclobutanil 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 1–day or single exposure. An acute dietary exposure assessment was performed for females 13 to 49 years old. No acute endpoint was identified for the general U.S. population or any other population subgroup.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated andcontain tolerance-level residues.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used USDA Pesticide Data Program (PDP) monitoring data for apple juice, bananas (not plantains) and milk. Tolerance level residues were used for all other registered and proposed uses. Average percent cropped treated (PCT) information was used for some commodities and 100 PCT information was used for all other registered and proposed uses.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, myclobutanil has been classified as ''Not likely to be carcinogenic to humans.'' Consequently, a quantitative cancer exposure and risk assessment is not appropriate for myclobutanil.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of 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 residues that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data 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 FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

a. 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.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

c. 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 40% apples (except juice); 15% almonds; 25% apricots; 55% artichokes; 5% asparagus; 1% green beans; 15% blackberries; 1% broccoli; 10% cantaloupes; 5% cauliflower; 35% cherries; 1% cucumber; 25% grapes; 65% hops; 1% mint; 10% nectarines; 10% peaches; 10% plums; 15% pumpkins; 25 % raspberries; 1% soybeans; 10% squash; 35% strawberries; 1% sugar beets; 5% tomatoes; and 5% watermelons.

The Agency used projected percent crop treated (PPCT) information for peppers estimating 46% of peppers are treated.

EPA estimates PPCT for myclobutanil use on peppers by assuming that the PCT during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the

dominant pesticide (i.e., the one with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant insecticide on the use site is selected for comparison with a new insecticide). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PPCT, based on the average PCT of the market leader is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. The predominant factors that bears on whether the estimated PPCT could be exceeded are whether the new pesticide use is more efficacious or controls a broader spectrum of pests than the dominant pesticides, whether there are concerns with pest pressures as indicated in emergency exemption requests or other readily available information, and whether the pathogenicity of the pest is prevalent in other states. All information currently available has been considered for myclobutanil, and it is the opinion of EPA that it is unlikely that actual PCT for myclobutanil will exceed the estimated PPCT during the next 5 years.

The Agency believes that the three conditions listed in Unit III.C.1.vi. have been met. With respect to Condition a, 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 b and c, 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 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 environmental fate 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of myclobutanil for acute exposures are estimated to be 120.1 parts per billion (ppb) for surface water and 2.83 ppb for ground water. The estimated environmental concentrations for chronic exposures are estimated to be 46.3 ppb for surface water and 2.83 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 120.1 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 46.3 ppb was used to access the contribution to drinking 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 currently registered for use on the following residential non-dietary sites: turf, ornamentals, and home garden uses on vegetables, fruit trees, nut trees, berries and mint. The risk assessment was conducted using the following residential exposure assumptions:

For adults, there is potential for short-term dermal and inhalation handler exposure, and short-term dermal post-application exposures from the residential uses of myclobutanil, including ''pick your own'' orchards, home fruit and vegetable gardens, and treated turf. Since myclobutanil is applied at 7- to 14–day intervals, only short-term exposure is expected for the residential handler. For children/toddlers, short-term dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as non-dietary ingestion/hand-to-mouth transfer of residues from turf grass. Intermediate-term post-application exposures may result for adults from dermal contact with treated fruits and vegetables at ''pick your own'' gardens, treated home fruit and vegetable gardens and treated turf. For toddlers, intermediate-term dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as non-dietary ingestion/hand-to-mouth transfer of residues from turf grass. Based on the current use patterns, no chronic residential exposures are 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) study data 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 exposure scenarios were assessed for residential post-application risks:

- Toddlers playing on treated turf;
- Adults performing yard work on treated turf;
- Adults playing golf on treated turf.

A total radioactive 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 to 0.68 lb active ingredient/Acre was use to assess the turf exposures.

Additional information on residential exposure assumptions can be found at *http://www.regulations.gov* in the document ''Myclobutanil. Human-Health Risk Assessment for Proposed Use on Section 3 Requests for Use on Snap Bean, Mint, Papaya, Gooseberry, Currant, Caneberry, Bell and Non-Bell Pepper, Head and Leaf Lettuce, and Artichoke,'' in docket ID number EPA–HQ–OPP–2007–0107.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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.''

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. 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, 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 EPA–HQ–OPP–2005–0497). Additional information regarding the uses proposed for myclobutanil in this action can also be found at *http://www.regulations.gov* in the following documents: 1,2,4 Triazole Revised Chronic and Acute Aggregate Dietary Exposure Assessments to Include for New Uses of Myclobutanil on Snap Bean, Mint, Papaya, Gooseberry, Currant, Caneberry, Bell and Non-Bell Pepper, Head and Leaf Lettuce, and Artichoke, and Triazole Alanine and Triazole Acetic Acid Revised Chronic and Acute Aggregate Dietary Exposure Assessments for New Uses of Myclobutanil on Snap Bean, Mint, Papaya, Gooseberry, Currant, Caneberry, Bell and Non-Bell Pepper, Head and Leaf Lettuce, and Artichoke in docket ID number EPA–HQ–OPP–2007–0107.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs 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 occurance control animals that occurred in the presence of 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 of 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 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 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. That decision is based on the following findings:

i. The toxicity database for myclobutanil is complete.

ii. There is no indication that myclobutanil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that myclobutanil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment (females 13 to 49 years old only) utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities. 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 commodities. 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. Finally, the residential handler assessment is based upon the residential standard operating procedures (SOPs) and utilized unit exposure data from the Outdoor Residential Exposure Task Force (ORETF) and the Pesticide Handler's Exposure Database (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 exposure to myclobutanil.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure for females 13 to 49 years old (no acute endpoint was identified for the general U.S. population or any other population subgroup), the acute dietary exposure from food and water to myclobutanil will occupy 4% of the aPAD for females 13 to 49 years old.

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 30% of the cPAD for children 1 to 2 years old, the subpopulation group with greatest exposure. Based on the use pattern, chronic residential exposure to residues of myclobutanil is not expected.

3. *Short-term risk and Intermediate-term risk*. Short-term and intermediate-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 and intermediate–term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for myclobutanil. As discussed in Unit III.C.3., short-term and intermediate-term exposures were assessed for adults and for children/toddlers. A NOAEL (10 mg/kg/day) from a 2-generation reproduction toxicity study in rats was used for assessing short-term and intermediate-term dermal, inhalation and incidental oral exposures; therefore, the short-term and intermediate-term aggregate risk estimates from the post-application exposure scenarios are the same for the general U.S. population and children/toddlers.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs ranging from 110 to 990: 110 for post-application exposures for adults for ''pick your own fruit'' operations; 120 for post-application exposures for adults to turf, heavy yard work; 130 post-application exposures for children playing on the lawn; 170 for adult handlers; 280 for adult post application exposures to home gardens; and 980 for adult post applications exposures while playing golf.

4. *Aggregate cancer risk for U.S. population*. The Agency has classified myclobutanil as 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.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to myclobutanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/nitrogen-phosphorus detector (GC/NPD) for myclobutanil and gas chromatography/electron-capture detection (GC/ECD) for the alcohol metabolite) is available to enforce the tolerance expression. The 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*.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican MRLs for myclobutanil.

C. Explanation of Tolerance Revisions

Based upon review of the data supporting the petitions, EPA revised the tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP) as follows: (1) PP 3E6562 from 3.0 ppm to 4.0 ppm for canistel; mango; papaya; sapodilla; sapote, black; sapote, mamey; and star apple; (2) PP 6E7138 from 4.5 ppm to 4.0 ppm for fruiting vegetables, crop group 8, except tomato and okra; from 11 ppm to 9.0 ppm for leafy vegetables, crop subgroup 4A, except spinach and cilantro; and from 0.9 ppm to 0.90 ppm for globe artichoke.

V. Conclusion

Therefore, tolerances are established for combined residues of myclobutanil and its alcohol metabolite on artichoke, globe at 0.90 ppm; canistel at 3.0 ppm; cilantro, leaves at 9.0 ppm; leafy greens, crop subgroup 4A, except spinach at 9.0 ppm; mango at 3.0 ppm; okra at 4.0 ppm; papaya at 3.0 ppm; sapodilla at 3.0 ppm; sapote, black at 3.0 ppm; sapote, mamey at 3.0 ppm; star apple at 3.0 ppm; and vegetable, fruiting, group 8, except tomato at 4.0 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: March 13, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.443 is amended by removing from the table in paragraph (b) the entries for artichoke, globe; beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, refined sugar; beet, sugar, roots; beet, sugar, tops; and pepper and by alphabetically adding commodities to the table in paragraph (a) to read as follows:

180.443 Myclobutanil; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	0.90
* * * * *	
Canistel	3.0

Commodity	Parts per million
* * * * *	
Cilantro, leaves	9.0
* * * * *	
Leafy greens, subgroup 4A, except spinach	9.0
Mango	3.0
* * * * *	
Okra	4.0
Papaya	3.0
* * * * *	
Sapodilla	3.0
Sapote, black	3.0
Sapote, mamey	3.0
* * * * *	
Star apple	3.0
* * * * *	
Vegetable, fruiting, group 8, except tomato	4.0

* * * * *

[FR Doc. E8–6205 Filed 3–25–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Inspector General

42 CFR Part 1008

Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by OIG

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, this final rule amends the OIG regulations at 42 CFR part 1008 by (1) revising the process for advisory opinion requestors to submit payments for advisory opinion costs, and (2) clarifying that notices to the public announcing procedures for processing advisory opinion requests will be published on OIG's Web site.

DATES: *Effective Date:* These regulations are effective on April 25, 2008.

Comment Period: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on April 25, 2008.

ADDRESSES: In commenting, please refer to file code OIG–223–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at *http://www.regulations.gov.* (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–223–IFC, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close period to Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 358–3141.

For information on viewing public comments, please see section IV in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Meredith Melmed, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 205 of Public Law 104–191

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–101, specifically required the Department to provide a formal guidance process to requesting individuals and entities regarding the application of the anti-kickback statute, the safe harbor provisions, and other OIG health care fraud and abuse sanctions. In accordance with section 205 of HIPAA, the Department, in consultation with the Department of Justice, issues written advisory opinions to parties with regard to: (1) What constitutes prohibited remuneration under the anti-kickback statute; (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Social Security Act (the Act), or established by regulation, for activities which do not result in prohibited remuneration; (3) what constitutes an inducement to reduce or limit services to Medicare or Medicaid program beneficiaries under section 1128A(b) of the Act [1]; and (4) whether an activity or proposed activity constitutes grounds for the imposition of civil or criminal sanctions under sections 1128, 1128A, or 1128B of the Act.

B. OIG Final Regulations

OIG published an interim final rule (62 FR 7350; February 19, 1997) establishing a new part 1008 in 42 CFR chapter V addressing various procedural issues and aspects of the advisory opinion process. In response to public comments received on the interim final regulations, we published a final rule (63 FR 38311; July 16, 1998) revising and clarifying various aspects of the earlier rulemaking. The rulemaking established procedures for requesting an advisory opinion. Specifically, the rule provided information to the public regarding costs associated with preparing an opinion and procedures for submitting an initial deposit and final payment to OIG for such costs.

II. Provisions of the Interim Final Rule

By statute, the Department must charge a fee equal to the costs incurred by the Department in responding to a request for an advisory opinion. (42 U.S.C. 1320a–7d(b)(5)(B)(ii)). Under the interim final and final advisory opinion rules, we directed requestors to make an initial payment to the U.S. Treasury by check or money order in the amount of $250. The regulations have also allowed for the acceptance of final payment of the fee by check or money order.

Through this interim final rule, we are setting forth several revisions to the payment process for advisory opinion requests. Specifically, we are modifying our procedures for submitting an advisory opinion request by deleting the current requirements at §§ 1008.31(b) and 1008.36(b)(6) for an initial payment of $250 for each advisory opinion request, and replacing the existing provision set forth in § 1008.31(b) with a requirement that payment for an advisory opinion be made directly to the Treasury of the United States, as directed by OIG. In addition, we are amending § 1008.43(d) to state that an advisory opinion will be issued following receipt by OIG of confirmation that payment in full has been remitted by the requesting party to the Department of Treasury as directed by OIG.

[1] Public Law 104–191 erroneously cited this provision as section 1128B(b) of the Act. Section 4331(a) of the Balanced Budget Act of 1997, Public Law 105–33, corrected this citation to section 1128A(b) of the Act.