2. In § 180.353, by revising the table in paragraph (b) to read as follows:

§ 180.353 Desmedipham; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
Red beet roots ..	0.2	8/31/99
Red beet tops ...	15	8/31/99

* * * * *

[FR Doc. 98–24844 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300705; FRL–6025–1]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of myclobutanil in or on artichokes, asparagus, and peppers (bell and non-bell). This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on artichokes, asparagus, and peppers (bell and non-bell) in California (all three commodities), Michigan (asparagus) and New Mexico (peppers). This regulation establishes a maximum permissible level for residues of myclobutanil in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on July 31, 2000.

DATES: This regulation is effective September 16, 1998. Objections and requests for hearings must be received by EPA on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300705], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300705], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300705]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the fungicide myclobutanil, in or on artichokes at 1.0 parts per million (ppm), asparagus at 0.02 ppm, and on peppers (bell and non-bell) at 1.0 ppm. These tolerances will expire and are revoked on July 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

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

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does

not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Use of Myclobutanil on Artichokes, Asparagus, and Peppers (Bell and Non-bell), and FFDCA Tolerances

The state of California requested specific exemptions for the use of myclobutanil on artichokes to control powdery mildew, on asparagus to control asparagus rust, and bell and non-bell peppers to control powdery mildew. Michigan requested a specific exemption for use of myclobutanil on asparagus to control asparagus rust. New Mexico requested a specific exemption for the use of myclobutanil on bell and non-bell peppers to control powdery mildew.

EPA has authorized under FIFRA section 18 the use of myclobutanil on artichoke to control powdery mildew in California, on asparagus to control asparagus rust in California and Michigan, and on peppers (bell and non-bell) for control of powdery mildew in California and New Mexico. After having reviewed these submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of myclobutanil in or on artichoke, asparagus, and bell and non-bell peppers. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on July 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on artichoke, asparagus, and peppers (bell and non-bell) after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether myclobutanil meets EPA's registration requirements for use on artichoke, asparagus, or on bell and non-bell peppers or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of myclobutanil by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than those already detailed within this document to use this pesticide on these crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for myclobutanil, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of myclobutanil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for the combined residues of myclobutanil on artichokes at 1.0 ppm, asparagus at 0.02 ppm, and peppers (bell and non-bell) at 1.0 ppm. EPA's assessment of the dietary 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. The nature of the toxic effects caused by myclobutanil are discussed below.

1. *Acute toxicity*. None. For acute dietary risk, EPA has not identified an acute dietary endpoint.

2. *Short - and intermediate - term toxicity.* For short-term dermal Margin of Exposure (MOE) calculations, the Agency used the systemic NOEL of 100 mg/kg/day from a 21–day dermal toxicity study in rats. This dose was the highest tested in the study. The Agency did not identify an inhalation endpoint.

For intermediate-term MOE calculations, the Agency used the NOEL of 10 miligrams/kilograms/day (mg/kg/day) from a 2–generation reproductive toxicity study in rats. At the Lowest Effect Level (LEL) of 50 mg/kg/day, there were decreases in pup body weight, an increased incidence in the number of stillborns, and atrophy of the prostate and testes.

3. *Chronic toxicity*. EPA has established the RfD for myclobutanil at 0.025 mg/kg/day. This RfD is based on a chronic feeding study in rats using a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. At the Lowest Observed Effect Level (LOEL) of 9.9 mg/kg/day there was testicular atrophy.

4. *Carcinogenicity*. Myclobutanil has been classified as a Group E chemical (no evidence of carcinogenicity for humans) by the Agency.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.443) for the combined residues of myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile plus its alcohol metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on a variety of raw agricultural commodities at levels ranging from 25.0 ppm in raisin waste to 0.02 ppm in cottonseed. Tolerances have also been established (40 CFR 180.443(b)) for the combined residues of myclobutanil plus its alcohol metabolite

(free and bound) and diol metabolite alpha-(4-chlorophenyl)-alpha-(3,4-dihydroxybutyl)-1*H*-1,2,4-triazole-1-propanenitrile, in meat, milk, poultry and eggs, at levels ranging from 0.02 ppm to 1.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from myclobutanil as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made somewhat conservative assumptions -- with the exception of bananas, all commodities having myclobutanil tolerances will contain myclobutanil and metabolite residues and those residues will be at the level of the established tolerance -- which results in an overestimate of human dietary exposure. For bananas an anticipated residue estimate was used. Percent crop-treated estimates were utilized for selected commodities included in the assessment. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment.

The existing myclobutanil tolerances (published, pending, and including the necessary section 18 tolerances) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Population Subgroup	ARC_{food} (mg/kg/day)	%Rfd
U.S. Population (48 states)	0.004283	17%
Nursing Infants (<1 year old)	0.006365	25%
Non-Nursing Infants (<1 year old)	0.018836	75%
Children (1-6 years old)	0.011508	46%
Children (7-12 years old)	0.006924	28%
Northeast Region	0.004573	18%
Western Region	0.004880	19%
Hispanics	0.005066	20%
Non-Hispanic Others	0.004443	18%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the Rfd occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water. Chronic exposure and risk* Based on information available to EPA, myclobutanil is persistent and not considered mobile in soils with the exception of sandy soils. Data are not available for its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile. There is no established Maximum Contaminant Level for residues of myclobutanil in drinking water. No Health Advisory Levels for myclobutanil in drinking water have been established. The ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, September 1992) has no information concerning myclobutanil.

EPA has estimated ground and surface water concentrations for myclobutanil based on the label rate of 0.65 lbs active ingredient (a.i.)/acre and assuming 15 applications per season. (The water numbers were based on turf.) The surface water numbers are based on the results of GENEEC model run. The ground water numbers are based on a screening tool, SCI-GROW, which tends to overestimate the true concentrations in the environment.

Surface water EEC based on the results of a GENEEC model run

Acute = 145.96 ppb (0.14596 ppm or mg/L)(maximum initial concentration)

Chronic = 118.6 ppb (0.1186 ppm or mg/L)(average 56-day concentration)

EPA divides the 90/56-day GENEEC value by 3 to obtain a value for chronic risk assessment calculations. Therefore, the surface water value for use in the chronic risk assessment would be 0.04 ppm or mg/L.

Ground water EEC (SCI-GROW estimate)

3.6 ppb (0.0036 ppm or mg/L) (use for both acute and chronic)

Chronic exposure from surface water is calculated below. Chronic exposure from ground water is lower.

EPA has calculated drinking water levels of concern (DWLOCs) for chronic (non-cancer) exposure to be 0.7 ppm for U.S. population, 0.6 ppm for Hispanics, and 0.06 ppm for non-nursing infants (<1 year old). To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to myclobutanil in drinking water.

The estimated average concentration of myclobutanil in surface water is 0.04 ppm. Chronic concentrations in ground water are not expected to be higher than the acute concentrations. The estimated average concentrations of myclobutanil in surface water are less than EPA's levels of concern for myclobutanil in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account the present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of myclobutanil in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

EPA bases this determination on a comparison of estimated concentrations of myclobutanil in surface waters and ground waters to back-calculated ''levels of concern'' for myclobutanil in drinking water. These levels of concern in drinking water were determined after EPA has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of myclobutanil in surface waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of myclobutanil on drinking water as a part of the aggregate risk assessment process.

3. *From non-dietary exposure.* Myclobutanil is currently registered for outdoor residential and greenhouse use on annuals and perennials, turf, shrubs, trees, and flowers. EPA has determined that these uses do not constitute a chronic exposure scenario, but may constitute a short- to intermediate-term exposure scenario (Note: the intermediate-term potential exposure would come from Post-application (dermal for adult; and dermal + ingestion of soil only, due to the persistence of the pesticide in soil, for toddlers). Other intermediate-term exposure scenarios are unlikely as dissipation is strongly influenced by the growth of the grass which needs weekly mowing (more frequently in spring) and most dissipation studies on lawns show considerable tailing off of residues by day 3 or 4; thus, the expectation of significant residues is very unlikely.

4. *Homeowner-use Products.* End-use products containing the active ingredient, myclobutanil, are marketed for homeowner use. The homeowner use with the greatest potential for exposure takes the form of small scale lawn application (other additional

application uses are on roses, flowers, ornamental shrubs and trees) of a soluble concentrate with a hose-end, backpack, or trigger bottle sprayer. Application of these products is recommended at two week intervals. Short-term (and not intermediate-term exposures, because of the amount of time it takes to mix, load, and apply this product) exposure is considered only. Short-term exposure, pre- and during application, will be considered an aggregate potential exposure: a summation of this exposure will include exposure levels for: the mixer + loader + applicator + Post-application on day zero (day of application). Short- and intermediate-term exposure will be considered during post-application (Note: Intermediate-term exposure is addressed only during post-application scenarios).

5. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether myclobutanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, myclobutanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that myclobutanil has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Chronic aggregate exposure and risk.* Using the partially refined exposure assumptions described above, EPA has concluded that aggregate exposure (food, water, and residential) to myclobutanil will not exceed EPA's level of concern. For the U.S. population, 17% of the RfD is occupied by dietary (food) exposure. The estimated average concentrations of myclobutanil in surface and ground water are less than EPA's levels of concern for myclobutanil in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of myclobutanil in drinking water do not contribute significantly to the aggregate chronic human health risk at the present time considering the present uses and uses proposed in this action. EPA has determined that the outdoor registered uses of myclobutanil would not fall under a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to myclobutanil residues.

2. *Short- and intermediate-term risk.* The short-term NOEL for dermal exposure is based on a dermal exposure toxicity study. Since the NOEL is based on a dermal study, oral exposures generally cannot be used directly to calculate a short-term aggregate exposure. However, because EPA determined that a dermal absorption factor of 100% should be used for risk assessment, oral exposures need not be multiplied by a modifying factor (converted to dermal equivalents) so that they can be compared to the dermal endpoint.

The chronic dietary exposure and calculated dietary MOE for the U.S. Population is as follows: MOE= 23,000, based on ARC of 0.004283 mg/kg/day.

The intermediate-term exposure scenarios and calculated MOE for the U.S.Population is as follows: MOE= 2,300, based on ARC of 0.004283 mg/kg/day.

There is a potential for short-term exposure from drinking water. However, as estimated average concentrations of myclobutanil in surface and ground water are less than EPA's levels of concern for drinking water as a contribution to chronic aggregate and acute aggregate exposures, contribution to short-term exposure should not exceed EPA's levels of concern either.

EPA concludes that short-term aggregate MOEs for adults are acceptable considering the default assumptions used in the derivation of exposure estimates and the fact that a LOEL was not identified in the 28-day rat dermal toxicity study the highest dose tested (HDT) was the NOEL in this study used to determine the MOE. Chemical-specific dissipation data and residential use/usage information are required to further refine these post-application exposure estimates.

D. Aggregate Cancer Risk for U.S. Population

Myclobutanil was classified by the Agency as a Group E chemical (no evidence of carcinogenicity for humans). Thus, a cancer risk assessment was not conducted.

E. Endocrine Disruptor Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At

that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Based on the adverse testicular findings, and increase in the number of stillborns, and a decrease in pup weight gain during lactation, in the chronic toxicity and reproduction studies in rats, myclobutanil should be considered as a candidate for evaluation as an endocrine disruptor.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* —i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental study in rats, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (fetal) NOEL was 93.8 mg/kg/day based on incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LOEL of 200 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LOEL of 50 mg/kg/day. The reproductive (pup) NOEL was 10 mg/kg/day, based on the increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for myclobutanil is complete with respect to current toxicological data requirements. Based on the developmental and reproductive toxicity studies discussed above, for myclobutanil there does not appear to be an extra sensitivity for pre- or post-natal effects.

v. *Conclusion*. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an factor is not needed to protect the safety of infants and children.

2. *Chronic risk.* Using the partially-refined exposure assumptions described above, EPA has concluded that aggregate exposure to myclobutanil from food ranges from 25% of the RfD for nursing infants (<1 year old), up to 75% for non-nursing infants (<1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to myclobutanil in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to myclobutanil residues.

3. *Short- or intermediate-term risk.* The short-term NOEL for dermal exposure is based on a dermal exposure toxicity study. Since the NOEL is based on a dermal study, oral exposures generally cannot be used directly to calculate a short-term aggregate exposure. However, because EPA determined that a dermal absorption factor of 100% should be used for risk assessment, oral exposures need not be multiplied by a modifying factor (converted to dermal equivalents) so that they can be compared to the dermal endpoint.

The chronic dietary exposure and calculated dietary MOE for infants (non-nursing, < 1 year old) is 5,300, based on ARC of 0.018836 mg/kg/day.

The dermal residential exposure is 0.85 mg/kg/day (reentry). The calculated dietary MOE for non-nursing infants (<1 year old) is 5,300.

For the short-term aggregate risk of the most highly exposed subgroup (non-nursing infants (<1 year old)), the calculated MOE is 120. There is a potential for short-term exposure from drinking water. However, as estimated average concentrations of myclobutanil in surface and ground water are less than EPA's levels of concern for drinking water as a contribution to chronic aggregate and acute aggregate exposures, contribution to short-term exposure should not exceed EPA's levels of concern either. EPA concludes that short-term aggregate MOEs for non-nursing infants (<1 year old) are acceptable.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residue of concern is myclobutanil plus its alcohol metabolite (free and bound), as specified in 40 CFR 180.443(a).

B. Analytical Enforcement Methodology

An adequate enforcement method is available to enforce the established tolerances. Quantitation is by Gas Liquid Chromatography (GLC) using an Nitrogen/Phosphorus detector for myclobu-tanil and an Electron Capture detector (Ni^{63}) for residues measured as the alcohol metabolite.

C. Magnitude of Residues

Residues of myclobutanil and its alcohol metabolite are not expected to exceed 1.0 ppm in/on artichoke, 0.02 ppm in/on asparagus, and 1.0 ppm in/on peppers (bell and non-bell), as a result of these section 18 uses. Secondary residues are not expected in animal commodities as no feedstuffs are associated with these section 18 uses. Meat/ milk/poultry/ egg tolerances have been established as a result of other myclobutanil uses.

D. International Residue Limits

There are no Codex, Canadian or Mexican residue limits established for myclobutanil and its metabolites on the commodities included in these section 18 requests. Thus, harmonization is not an issue for these section 18 actions.

E. Rotational Crop Restrictions.

Information concerning the likelihood of residues in rotational crops is not currently available for myclobutanil, although such data is expected to be submitted to EPA shortly. Until EPA has reviewed and approved such data, the Agency has required that the following restriction should be added to the label for approved section 18 uses: Rally treated fields can be rotated at any time to crops which are included on the Rally label. For crops not listed on the registered label, do not plant new crops on treated fields for these periods: leafy vegetables, small grains -- 120 days root vegetables, all other crops -- 210 days.

VI. Conclusion

Therefore, the tolerance is established for combined residues of myclobutanil in artichoke at 1.0 ppm, asparagus at 0.02 ppm, and bell and non-bell peppers at 1.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 16, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300705] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408(d) 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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition,

Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: August 26, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority : 21 U.S.C. 346a and 371.

2. In section 180.443, by adding new entries for artichokes, asparagus, and peppers (bell and non-bell) in alphabetical order to the table in paragraph (b), to read as follows:

§ 180.443 Myclobutanil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Artichoke	1.0	7/31/00
Asparagus	0.02	7/31/00
*	*	*
Peppers (bell and non-bell)	1.0	7/31/00
*	*	*

* * * * *

[FR Doc. 98–24845 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300699; FRL–6022–5]

RIN 2070–AB78

Propyzamide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propyzamide (pronamide) and its metabolites containing the 3,5-dichlorobenzoyl moiety (calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on cranberries, grass hay, and grass forage. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal