

Commodity	Parts Per Million (ppm)
* * *	* * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* * * *

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read.

Authority: 21 U.S.C. 346a and 348.

§ 185.3500 [Removed]

b. In § 185.3500 by transferring the entries in the tables to paragraphs (a)(1), (2), and (3), and alphabetically adding them to the table in paragraph (a) of § 180.364, and by removing the remainder of § 185.3500.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 185 continues to read.

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.3500 [Removed]

b. In § 186.3500 by transferring the entries in the tables to paragraphs (a) and (b) and alphabetically adding them to the table in paragraph (a) of § 180.364, and by removing the remainder of § 186.3500.

[FR Doc. 97-9231 Filed 4-10-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP-300466; FRL-5597-9]

RIN 2070-AC78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the fungicide myclobutanil in or on the raw agricultural commodity strawberries in connection with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of myclobutanil on

strawberries in Florida. This regulation establishes a maximum permissible level for residues of myclobutanil in this food pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and be revoked by EPA on March 31, 1998.

DATES: This regulation becomes effective April 11, 1997. Objections and requests for hearings must be received by EPA on June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP], 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 document control number, [OPP], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), 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. 1132, 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP]. 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: Stephen Schaible, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA

22202. (703) 308-8337, e-mail: schaible.stephen@epamail.epa.gov. **SUPPLEMENTARY INFORMATION:** EPA, 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 a tolerance for residues of the fungicide myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound), hereafter referred to as myclobutanil, in or on strawberries at 0.5 part per million (ppm). This tolerance will expire and be revoked on March 31, 1998.

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 CFR 58135, November 13, 1996)(FRL-5572-9).

New section 408(b)(2)(A)(i) 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, 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) 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemption for Myclobutanil on Strawberries and FFDCA Tolerances

On January 14, 1997 the state of Florida availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of myclobutanil on strawberries to control powdery mildew (*Sphaerotheca fuliginea*). Florida stated that emergency conditions developed due to planting of powdery mildew-infected transplants purchased from Canadian suppliers and

the occurrence of weather conditions conducive to disease development. Florida claims that the registered alternatives are either not efficacious or are phytotoxic. Without the use of myclobutanil, it is claimed that strawberry growers will suffer severe economic losses.

As part of its assessment of this crisis declaration, EPA assessed the potential risks presented by residues of myclobutanil in or on strawberries. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemption only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. This tolerance for myclobutanil will permit the marketing of strawberries treated in accordance with the provisions of the section 18 emergency exemption. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although this tolerance will expire and be revoked on March 31, 1998, under FFDCA section 408(l)(5), residues of myclobutanil not in excess of the amounts specified in the tolerance remaining in or on strawberries after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemption. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether myclobutanil meets the requirements for registration under FIFRA section 3 for use on strawberries, or whether a permanent tolerance for myclobutanil for strawberries would be appropriate. This action by EPA does not serve as a basis for registration of myclobutanil by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than Florida to use this product on this crop 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. For many of these 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 percent or less of the RfD) is generally considered acceptable by EPA.

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 margin of exposure 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.

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, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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. 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 percent of every crop considered in the analysis is treated with the pesticide being evaluated. 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 and that the market for pest control on any given crop seldomly belongs to a single pesticide.

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.

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. Myclobutanil is already registered by EPA for numerous food and feed uses, as well as residential use on annuals and perennials, turf, shrubs and trees, and African violets (indoor). EPA has received a petition requesting establishment of a tolerance for myclobutanil on strawberries. The time-limited tolerance associated with the current emergency exemption does not

constitute a decision regarding the pending petition for tolerance on strawberries. For the purposes of this emergency exemption, 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 a time-limited tolerance for residues of myclobutanil on strawberries at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing this tolerance follows.

A. Toxicological Profile

1. *Chronic toxicity.* The RfD of 0.025 milligrams per kilogram per day (mg/kg/day) was established by the Agency based on the chronic feeding study in rats with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. There was testicular atrophy at the lowest effect level (LEL) of 9.9 mg/kg/day.

2. *Acute toxicity.* The Office of Pesticide Programs (OPP) has determined that data do not indicate the potential for adverse effects after a single dietary exposure.

3. *Short-term toxicity.* OPP has determined that short- and intermediate-term risk assessments are appropriate for occupational and residential routes of exposure. OPP recommends that the NOEL of 100 mg/kg/day, taken from the 21-day dermal toxicity study in rats, be used for the short term dermal MOE calculations. This dose level was the highest tested in the study. For intermediate term MOE calculations, OPP recommended using the NOEL of 10 mg/kg/day from the 2-generation rat study. Effects seen at the LEL in this study (50 mg/kg/day) were decreases in pup body weight, an increased incidence in number of stillborns, and atrophy of the prostate and testes. Though these endpoints have been identified, no acceptable reliable exposure data to assess these potential risks are available at this time.

4. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified myclobutanil as Group E chemical - "no evidence of carcinogenicity for humans" - based on the results of carcinogenicity studies in two species. The doses tested are adequate for identifying a cancer risk.

B. Aggregate Exposure

Established U.S. tolerances for myclobutanil and its alcohol metabolites (free and bound) are found in 40 CFR 180.443, and range from 0.05 ppm for milk to 5 ppm for cherries (sweet and sour). The proposed time-limited tolerance of 0.5 ppm is based on

residue field trial data on strawberries submitted in support of PP# 4E4302. There are no livestock feed items associated with the proposed use on strawberries, so no additional livestock dietary burden will result from this section 18 registration. Therefore, existing meat, milk, and poultry tolerances are adequate.

For the purpose of assessing potential chronic dietary exposure from myclobutanil, EPA generally assumed tolerance level residues and percent of crop treated refinements to estimate the Anticipated Residue Contribution (ARC) from the proposed and existing food uses of myclobutanil. The use of percent of crop treated data for most of the existing food uses in this analysis, as well as the use of refined residue information for the existing use on bananas, results in a more refined estimate of exposure than the TMRC.

In conducting this exposure assessment, EPA has made conservative assumptions—most all foods considered in the analysis were assumed to have myclobutanil residues present at the level of the tolerance. Percent crop treated data were used for many commodities with existing myclobutanil tolerances (stone fruits, pome fruits, grapes, and cottonseed) in the chronic exposure assessment, but were not considered when calculating the dietary burden from which secondary residue tolerances in meat, milk and poultry were derived or for the proposed use on strawberries. Thus, in making a safety determination for the subject section 18 tolerances, EPA is taking into account this conservative exposure assessment.

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Review of terrestrial field dissipation data by the Agency indicates that myclobutanil did not leach into groundwater in either sandy loam or coastal soil. There is no established Maximum Concentration Level for residues of myclobutanil in drinking water. No drinking water health advisories have been issued for myclobutanil. The "Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992) has no information concerning myclobutanil.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk

assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure to contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause myclobutanil to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with myclobutanil in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

There are residential uses of myclobutanil and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational exposure scenarios. OPP has identified toxicity endpoints for short- and intermediate-term residential risk assessment. However, no acceptable, reliable exposure data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make its safety determination for this tolerance based on those factors which it can reasonably integrate into a risk assessment.

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. Determination of Safety for U.S. Population

EPA has calculated that chronic dietary exposure to myclobutanil will

utilize 14 percent of the RfD for the U.S. population. Available information indicate that there will be little, if any exposure to myclobutanil in drinking water and EPA has no reliable exposure information regarding the level of exposure to myclobutanil from non-occupational, non-dietary sources. EPA generally has no concern for exposures below 100 percent 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. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to myclobutanil residues.

D. Determination of Safety for Infants and Children

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 2-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.

From the rat developmental study, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the lowest observed effect level (LOEL) of 312.6 mg/kg/day. The developmental (pup) NOEL was 93.8 mg/kg/day, based on increased incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day. From the rabbit developmental study, 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 (pup) 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 LEL of 200 mg/kg/day.

From the rat reproduction study, the maternal (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 LEL of 50 mg/kg/day. The reproductive (parental) NOEL was 10 mg/kg/day, based on increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

FFDCA section 408 provides that EPA shall apply an additional uncertainty factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines, based on reliable data, that a different uncertainty factor would be appropriate. Generally, EPA believes that reliable data support using the standard hundredfold uncertainty factor for extrapolating from animal studies to humans, where there is a complete data base and the effects of concern are not such to indicate such a hundredfold uncertainty factor is inadequate. Based on current toxicological data requirements, the data base for myclobutanil relative to pre- and post-natal toxicity is complete. The Agency notes that there is approximately a 25-fold difference between the developmental NOEL of 60 mg/kg/day from the rabbit developmental toxicity study and the NOEL of 2.5 mg/kg/day from the chronic rat feeding study which was the basis of the RfD. It is further noted that in both the rabbit and rat developmental toxicity studies, the developmental NOEL and maternal NOEL are the same (60 mg/kg/day for the rabbit and 93.8 mg/kg/day for the rat). In the rat reproduction study, the maternal NOEL (2.5 mg/kg/day) was four times lower than the developmental (pup) and reproductive NOELs (10 mg/kg/day). These studies indicate that there does not appear to be additional sensitivity for infants and children in the absence of maternal toxicity and that there is no concern that a hundredfold uncertainty factor will be inadequate. EPA concludes that a hundredfold uncertainty factor is appropriate for infants and children.

EPA has calculated that the percent of the RfD that will be utilized by chronic dietary exposure to residues of myclobutanil ranges from 22 percent for children 7 to 12 years old, up to 73 percent for non-nursing infants. Given that aggregate exposure is still below the Agency's level of concern, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to myclobutanil residues.

V. Other Considerations

The metabolism of myclobutanil in plants and animals is adequately understood for the purposes of this tolerance. There is no Codex maximum residue level established for residues of myclobutanil on strawberries. There is a practical analytical method for detecting and measuring levels of myclobutanil in or on food with a limit of detection that allows monitoring of food with residues

at or above the levels set in this tolerance. EPA has provided information on this method to the Food and Drug Administration. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-5805.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemption is established for residues of myclobutanil in strawberries at 0.5 ppm. This tolerance will expire on March 31, 1998.

In addition to the new tolerance being established, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in §§ 185.4350 and 186.4350 with the tolerances in § 180.443 and is eliminating §§ 185.4350 and 186.4350.

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 June 10, 1997 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 Docket

A record has been established for this rulemaking under docket number [OPP]. A public version of this record, 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 Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply.

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects**40 CFR Part 180**

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

40 CFR Part 185

Environmental protection, Food and additives, Pesticides and pest.

40 CFR Part 186

Environmental protection, Animal feeds Pesticides and pest.

Dated: April 4, 1997.

Penelope A. Fenner-Crisp,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. Section 180.443 is amended as follows:

i. In paragraph (a) by adding the heading.

ii. In paragraph (b) by transferring and alphabetically adding the entry in the table to the table in paragraph (a) and by removing the remaining text.

iii. In paragraph (c) by transferring and alphabetically adding the entries in the table to the table in paragraph (a) and by removing the remaining text.

iv. By redesignating paragraph (d) as paragraph (b) and by revising newly redesignated paragraph (b).

v. By adding the headings and reserving new paragraphs (c) and (d).

§ 180.443 Myclobutanil; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide myclobutanil, in connection with use of the pesticide under section 18 emergency exemption granted by EPA. The tolerances are specified in the following table. These tolerances expire and are automatically revoked on the date specified in the table.

Commodity	Parts per million	Expiration/Revocation Date
Cucurbit vegetables	0.3	November 30, 1997
Strawberries	0.5	March 31, 1998

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.4350 [Removed]

b. The entries in the table to § 185.4350 are transferred and added alphabetically to the table in paragraph (a) of § 180.443; the remainder of § 185.4350 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.4350 [Removed]

b. The entries in the table to § 186.4350 are transferred and added alphabetically to the table in paragraph (a) of § 180.443; the remainder of § 186.4350 is removed.

[FR Doc. 97-9378 Filed 4-11-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 180, 185, and 186**

[OPP-300467; FRL-5598-7]

RIN 2070-AB78

Sethoxydim; Extension of Time-limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document extends the effective dates for the established time-limited tolerances for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (also referred to in this document as sethoxydim) and its metabolites in or on various raw agricultural commodities. The Interregional Research Project Number 4 (IR-4) requested these time extensions under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation becomes effective April 11, 1997. Objections and hearing request must be received by June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300467; PP OE3909, 2E4052, 2E4065, 2E4092, and 3E4162], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M