

EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State submittal/approval date	EPA approval date	Explanation
*	*	*	*	*
Chapter 115 (Regulation 5)—Control of Air Pollution from Volatile Organic Compounds				
*	*	*	*	*
Subchapter F Miscellaneous Industrial Sources				
Cutback Asphalt				
Section 115.510	Definitions	August 18, 1999/August 31, 1999.	December 22, 1999 and 64 FR 71670.	
*	*	*	*	*
Section 115.512	Control Requirements	August 18, 1999/August 31, 1999.	December 22, 1999 and Federal Register cite.	
Section 115.513	Alternative Control Requirements.	August 18, 1999/August 31, 1999.	December 22, 1999 and 64 FR 71670.	
*	*	*	*	*
Section 115.515	Testing Requirements	August 18, 1999/August 31, 1999.	December 22, 1999 and 64 FR 71670.	
Section 115.516	Recordkeeping Requirements.	August 18, 1999/August 31, 1999.	December 22, 1999 and 64 FR 71670.	
Section 115.517	Exemptions	05/08/92	03/07/95 60 FR 12438	Ref 52.2299(c)(88).
*	*	*	*	*
Section 115.519	Counties and Compliance Schedules.	05/08/92	03/07/95 60 FR 12438	Ref 52.2299(c)(88).
*	*	*	*	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300957; FRL-6398-2]

RIN 2070-AB78

Myclobutanil; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for combined residues of the fungicide myclobutanil and its metabolites in or on hops at 5.0 parts per million (ppm) for an additional 2-year period. This tolerance will expire and is revoked on December 31, 2001. This regulation also extends time-limited tolerances for combined residues of the fungicide myclobutanil and its metabolites, in or on caneberries at 1.0 ppm and in or on peppermint and spearmint at 2.5 ppm for an additional 1-year period. These tolerances will

expire and are revoked on December 31, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on caneberries, hops, peppermint and spearmint. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (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.

DATES: This regulation is effective December 22, 1999. Objections and requests for hearings, identified by docket control number OPP-300957, must be received by EPA on or before February 22, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-

300957 in the subject line on the first page of your response.

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; telephone number: (703) 308-9358; and e-mail address: Deegan.Dave@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the Federal Register listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300957. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA a final rule, published in the **Federal Register** of July 10, 1998 (63 FR 37289) (FRL-5798-6), which announced that on its own initiative under section 408 of FFDCA, 21 U.S.C. 346a, as amended by the Food Quality Protection

Act of 1996 (FQPA) (Public Law 104-170) it established a time-limited tolerance for the combined residues of myclobutanil and its metabolites in or on hops at 5.0 ppm, and caneberries at 1.0 ppm with an expiration date of December 31, 1999. In the **Federal Register** of July 17, 1998 (63 FR 38481) (FRL-6016-8), a time-limited tolerance for myclobutanil and its metabolites was established in or on peppermint and spearmint at 2.5 ppm, with an expiration date of January 31, 2000. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received requests to extend the use of myclobutanil on hops, caneberries, and mint for this year's growing season, due to the ongoing difficulties of controlling powdery mildew on hops and mint, peppermint rust on mint, and of orange rust on caneberries. EPA's review of these exemption requests have concluded that there are no other readily-available means to effectively control these pest situations at the current time. After reviewing each of these submissions, EPA concurs that emergency conditions existed, and EPA authorized the requested uses of myclobutanil under provisions of FIFRA section 18.

EPA's assessed the potential risks presented by residues of myclobutanil in or on caneberries, hops, and mint. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule published in the **Federal Register** of July 10, 1998 (63 FR 37289). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended for an additional 1 or 2-year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on December 31, 2000, or December 31, 2001, under FFDCA section 408(l)(5),

residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on the commodities after the expiration date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. 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.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300957 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 22, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so

marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-300957, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

IV. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408 in response to a FIFRA section 18 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) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and*

Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final

rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 8, 1999.

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. 321(q), 346(a) and 371.

2. In § 180.443, by amending the table in paragraph (b), by revising the following entries to read as follows:

§ 180.443 Myclobutanol; tolerances for residues.

(b) * * * * *

Commodity	Parts per million	Expiration/revocation date
Caneberries	1.0	12/31/00
Hop cones, dried ..	5.0	12/31/01
Peppermint	2.5	12/31/00
Spearmint	2.5	12/31/00

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 422

[HCFA-1011-F]

RIN 0938-A183

Medicare Program; Solvency Standards for Provider-Sponsored Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: The Balanced Budget Act of 1997 established a new Medicare+Choice (M+C) program that offers eligible individuals Medicare benefits through enrollment in one of an array of private health plans that contract with us. Among the new options available to Medicare beneficiaries is enrollment in a provider-sponsored organization (PSO). This final rule revises and responds to comments on solvency standards that certain entities must meet to contract as PSOs under the new M+C program. These standards, originally established in an interim final rule published on May 7, 1998, apply to PSOs that have received a waiver of the requirement that M+C organizations must be licensed by a State as risk-bearing entities.

DATES: *Effective date:* These regulations are effective on January 21, 2000.

FOR FURTHER INFORMATION CONTACT: Marty Abeln, (410) 786-1032.

SUPPLEMENTARY INFORMATION:

I. Background—Balanced Budget Act of 1997 and the Medicare+Choice Program

Section 4001 of the Balanced Budget Act (BBA) (Public Law 105-33), enacted August 5, 1997, added a new Part C (sections 1851 through 1859) to title XVIII of the Social Security Act (the Act), establishing the "Medicare+Choice" (M+C) program. Under Part C, M+C eligible individuals (generally individuals with both Part A and Part B coverage who do not have End Stage Renal Disease (ESRD) may elect to receive their Medicare benefits through private health plans (M+C organizations) that choose to contract with HCFA. M+C organizations may offer one or more M+C plans of one of three types. Under "coordinated care plans," beneficiaries receive benefits through a network of providers, as in the case of an health maintenance organization (HMO) or preferred provider organization (P.O.). A "provider sponsored organization" (PSO), which is owned by providers through which it provides benefits, and which is the subject of this final rule, necessarily offers a coordinated care plan. (See section 1851(a)(2)(A) of the Act). Other M+C plan options provided for in Part C, but not yet offered by any M+C organization, are private-fee-for service plans and medical savings account (MSA) plans (that is, a combination of a high deductible, catastrophic insurance plan with a contribution to an M+C MSA account).

Interim final regulations for the overall implementation of the M+C program were published in the **Federal Register** on June 26, 1998 (63 FR 34968) and are set forth in part 422 of title 42 of the Code of Federal Regulations (CFR). Provisions enacted by the BBA and implemented in the interim final M+C regulations establish broad and comprehensive requirements for contracting as an M+C organization, including basic benefits, payment, access to service, quality assurance, beneficiary hold harmless, continuation of benefits, appeals mechanisms, marketing, and enrollment processes. These overall M+C regulations apply to M+C organizations that are PSOs.

A PSO is described in section 1855(d) of the Act as a public or private entity—

- That is established or organized, and operated, by a health care provider or group of affiliated health care providers;
- That provides a substantial proportion of the health care items and services directly through the provider or affiliated group of providers; and
- With respect to which the affiliated providers share, directly or indirectly, substantial financial risk for the provision of these items and services and have at least a majority financial interest in the entity.

On April 14, 1998, we published an interim final rule in the **Federal Register** at 63 FR 18124, titled "Definition of Provider-Sponsored Organization and Related Requirements" with an opportunity for public comment setting out the PSO definition, clarifying certain terms, and establishing related requirements. This PSO definitions rule established 42 CFR part 422 and subpart H of that part, dealing with PSOs. The terms and requirements related to the definition of a PSO are now found at §§ 422.350 through 422.356. On May 7, 1998, we published an interim final rule in the **Federal Register** at 63 FR 25360 titled "Waiver Requirements and Solvency Standards for Provider Sponsored Organizations," establishing solvency requirements that apply to PSOs that obtain a waiver of the M+C State licensure requirement and setting forth procedures and standards that apply to requests for the waivers. The solvency portion of the interim final PSO regulation was based on the work of the PSO negotiated rulemaking committee, as required at section 1856(a) of the Act, which provides that the Secretary establish through a negotiated rulemaking process the solvency standards that entities will be required to meet if they obtain a waiver of the otherwise applicable requirement that