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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-2002-0142; FRL-7187-4]

**1-Methylcyclopropene; Exemption from the Requirement of a Tolerance**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of 1-Methylcyclopropene (1-MCP) in or on fruits and vegetables when used as a post harvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene. AgroFresh, Inc. (formerly BioTechnologies for Horticulture) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1-MCP.

**DATES:** This regulation is effective July 26, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0142, must be received on or before September 24, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0142 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Driss Benmhend, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9525; e-mail address: Benmhend.driss@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:

Categories	NAICS codes	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," "Regulations and Proposed Rules," 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/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html).

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0142. 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, 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**

In the *Federal Register* of June 21, 2000 (65 FR 38550) (FRL-6589-5), EPA issued a notice pursuant to section 408(d)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d)(3), as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP OF6144) by AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.), 100 Independence Mall West, Philadelphia, PA 19106-2399. As required by section 408(d)(2)(A)(i)(I), this notice included a summary of the petition prepared by the petitioner AgroFresh, Inc. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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. . . ." Additionally, section 408(b)(2)(D) requires that 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."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First,

EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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 end-use product, a white powder, when mixed with water or a buffer solution releases the gas 1-MCP. The active ingredient acts as an inhibitor to ethylene, by blocking the attachment of ethylene to tissue, and thus, prolongs the life of the food commodity treated.

Toxicity studies submitted in support of the tolerance exemption petition, and the Agency reviews are compiled in the official record established for this action under the docket ID number OPP-2002-0142.

1. *Acute toxicity (MRIDs 444647-04 to 08)*. 1-MCP exhibits low acute toxicity. It is a category IV biopesticide. The rat oral LD<sub>50</sub> is greater than 5,000 milligrams/kilograms (mg/kg), the rabbit dermal LD<sub>50</sub> is greater than 2,000 mg/kg and the rat inhalation LC<sub>50</sub> is greater than 2.5 milligram/liter (mg/L) (or greater than 1,126 parts per million (ppm) v/v active ingredient in air). No deaths or clinical signs of systemic toxicity were observed following these acute exposures. 1-MCP produces minimal irritation of skin and eyes in rabbits and 1-MCP is not a skin sensitizer. No hypersensitivity incidents were observed following exposure to 1-MCP.

2. *Genotoxicity (MRID 444647-09)*. 1-MCP was not mutagenic when tested as a gas in several short-term *in vitro/in vivo* assays, including a bacterial reverse mutation assay (Ames test), an *in vitro* mammalian point mutation assay in Chinese hamster ovary cells, an *in vitro* cytogenetics assay in human lymphocytes and an *in vivo* mouse micronucleus assay following inhalation exposure. In addition, 1-MCP is not mutagenic when tested as a suspension in cell media in the Ames test and in the *in vitro* mouse lymphoma forward mutation assay (MRID 444647-10) and is not mutagenic in the *in vivo* mouse micronucleus assay (MRID 444747-11) following oral exposure (gavage).

3. *Developmental toxicity (MRID 454586-08)*. 1-MCP produces no developmental toxicity when tested in a standard developmental toxicity study in the rat via inhalation at concentrations up to and including 2.3 mg a.i./L (or 543 mg a.i./kg/day, 6 hr exposure/day). The no observed adverse effect level (NOAEL) for maternal toxicity was 0.24 mg a.i./L (56 mg a.i./kg/day, 6 hr exposure/day).

4. *Subchronic toxicity (MRID 456090-01)*. 1-MCP was tested in a 90-day inhalation study at doses of 0.05, 0.24 and 2.3 mg a.i./kg in the rat. The NOAEL is 0.05 mg a.i./L (equivalent to 9 to 15 mg a.i./kg/day), based on minimal to mild effects on spleen and kidney histopathology at 0.24 mg a.i./L (equivalent to 39 to 66 mg a.i./kg/day). In this study there was no evidence of neurotoxicity, no effects on the respiratory tract and no effects on pathology of any endocrine or reproductive organs up to and including the highest dose tested of 2.3 mg a.i./L (or equivalent to 380 to 640 mg a.i./kg/day).

5. AgroFresh (the applicant) submitted a waiver request for the immune response data requirements based on the current toxicological data submitted on 1-MCP. The review of the 3-month inhalation rat study (mentioned in the previous paragraph) indicates, no effects on thymus weight and no effects on the histopathology of the thymus, bone marrow or spleen that would be attributed to an impact on the immune system were seen. There were no effects on white blood cell differential parameters (including monocytes, lymphocytes, segmented neutrophils or eosinophils) and no basophils were observed which may be indicative of an allergic reaction. The Agency concluded that 1-MCP did not induce dysfunction or inappropriate suppressive responses in components of the immune system. As a result, immune response data requirements were waived.

6. *Other*. 1-MCP has a mode of action in plants which is a non-persistent and non-toxic mode of action. 1-MCP prevents the natural chemical, ethylene, from binding to ethylene receptors in plants. This mode of action is not relevant in animals, since ethylene receptors are not present in animal tissues.

### IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including

drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

#### A. Dietary Exposure

1. *Food—From food and feed uses*. The primary source for human exposure to 1-MCP will be from ingestion of the following raw food commodities and the processed food commodities derived from: apples, melons, tomatoes, pears, avocados, mangoes, papayas, kiwifruit, plums, apricots and persimmons. Studies submitted (MRID 456090-02) showed residues in treated apples to be extremely low (average residue was 0.004 ppm using an exaggerated treatment rate of 1,200 parts per billion (ppb) versus the 1,000 ppb proposed label rate). A worst-case scenario (using the 0.004 ppm average residue concentration found in treated apples and assuming that concentration is present in 100% of the diet regardless of crops treated) indicates that a daily diet of 1.5 kg/day could contain 0.006 mg 1-MCP. For the general population (assuming an average body weight of 60 kg), this would represent a daily intake of 0.0001 mg 1-MCP/kg body weight which is 90,000 to 150,000-fold less than the 9-15 mg/kg NOAEL indicated in the 90-day inhalation study.

Residues in other treated commodities are expected to be similar or even lower since the highest treatment rate is recommended for apples. Processing would be expected to further lower the residue levels in processed food commodities.

2. *Drinking water exposure*. Since 1-MCP will only be used on post-harvested fruits and vegetables in enclosed storage areas, there is little if any, potential for drinking water exposure.

#### B. Other Non-Occupational Exposure

The potential for non-dietary exposure to 1-MCP for the general population, is unlikely because potential use sites are commercial, agricultural, and horticultural. 1-MCP is currently registered for indoor, nonfood commercial use on flowers and ornamentals. The Agency has approved that use, based on the data submitted that show little potential for significant non-occupational exposure to the general population.

1. *Dermal exposure*. 1-MCP will only be sold enclosed in a generator for treatment of raw agricultural commodities. The generator will not release 1-MCP until the applicator has exited the storage area and entrances to the treatment area have been sealed. At

the end of the treatment period, the storage area will be vented before workers are permitted to reenter the area. This label mitigating language would eliminate the potential for dermal exposure to handlers or applicators.

2. *Inhalation exposure.* As mentioned in the previous paragraph, the use of this product according to the label instructions would result in little, if any, inhalation exposure to handlers or applicators.

#### V. Cumulative Effects

The Agency has considered the cumulative effects of 1-MCP and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. There is no indication of mammalian toxicity at the maximum doses tested, of this or other products containing 1-MCP.

#### VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population.* There is reasonable certainty that no harm will result from aggregate exposure to residues of 1-MCP to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Categories III and IV) and the minimum exposure associated with 1-MCP's use.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that 1-MCP is practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, based on the lack of observed developmental toxicity and extremely low exposure, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to 1-MCP residues. Exemption of 1-MCP from the

requirements of a tolerance should pose no significant risk to humans or the environment

#### VII. Other Considerations

##### A. Endocrine Disruptors

EPA is required under the FFDCA as amended by FQPA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen- and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, 1-MCP may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of 1-MCP. In addition, 1-MCP does not share any structural similarity to any known endocrine disruptive chemical.

##### B. Analytical Method(s)

EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including 1-MCP's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for 1-MCP.

##### C. Codex Maximum Residue Level

No Codex maximum residue levels are established for residues of 1-MCP in or on any food or feed crop. There are no established tolerances or exemptions

from tolerance for 1-MCP in the United States. The Agency has classified 1-MCP as a biochemical pesticide.

#### VIII. Conclusions

Based on the toxicology data submitted, there is reasonable certainty no harm will result from aggregate exposure of residues of 1-MCP to the U.S. population, including infants and children, when the proposed product is used in accordance with label instructions and good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which reliable data were submitted, accepted and reviewed. The Agency has arrived at this conclusion based on the data submitted demonstrating no toxicity at the maximum doses tested. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of 1-MCP in or on all food commodities.

#### IX. 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 ID number OPP-2002-0142 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 September 24, 2002.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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](mailto: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, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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 IX.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 ID number OPP-2002-0142, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., 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](mailto: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 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).

#### **X. Regulatory Assessment Requirements**

This final rule establishes an exemption from the tolerance requirement under FFDC 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose

any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the tolerance exemption 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 FFDC section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with*

*Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### **XI. 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 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: July 16, 2002.

**Marcia E. Mulkey,**

*Director, 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 374.

2. Section 180.1220 is added to subpart D to read as follows:

#### **§ 180.1220 1-Methylcyclopropene; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of 1-Methylcyclopropene in or on fruits and vegetables when used as a post harvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene.

[FR Doc. 02-18868 Filed 7-25-02; 8:45am]

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### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Centers for Medicare & Medicaid Services**

#### **42 CFR Part 405**

[CMS-3074-F2]

**RIN 0938-AK98**

#### **Medicare Program; End-Stage Renal Disease: Removing of Waiver of Conditions for Coverage Under a State of Emergency in the Houston, Texas Area**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS).

**ACTION:** Final rule.

**SUMMARY:** This final rule removes an emergency waiver of the Medicare end-stage renal disease (ESRD) conditions for coverage granted to permit the transplant team of an approved renal transplant center to furnish kidney transplant services in three specific hospitals in the Houston, Texas area during a state of emergency. The state of emergency has ceased, the primary kidney transplant center in the area is now fully operational, and the effective period of the waiver provisions has expired.

**EFFECTIVE DATE:** July 26, 2002.

**FOR FURTHER INFORMATION CONTACT:** Rachael Weinstein, (410) 786-6775

#### **SUPPLEMENTARY INFORMATION**

##### **I. Provisions of This Rule**

On June 20, 2001, we published a final rule in the **Federal Register** (66 FR 33030-33031) that granted an emergency waiver of the Medicare end-stage renal disease (ESRD) conditions of coverage to permit the transplant team of an approved renal transplant center to furnish covered kidney transplant services in three specific hospitals in the Houston, Texas area during a state of emergency. The state of emergency (a

natural disaster due to flooding) resulted in a severe health and safety threat to hospitals in the entire Houston, Texas area, including ESRD facilities that were approved to furnish kidney transplant services. Waivers of the conditions of coverage were granted to Memorial Hermann-Memorial City Hospital, Memorial Hermann Southwest Hospital, and Memorial Hermann Southeast Hospital to permit an approved transplant team to furnish kidney transplant services in the three hospitals, effective June 15, 2001, through the earlier of December 15, 2001, or until Memorial Hermann Hospital, the primary kidney transplant center, reopened.

Memorial Hermann Hospital is now reopened. In the June 20, 2001 final rule, we amended the Medicare regulations to include a new § 405.2175 that incorporated the waiver provisions. In § 405.2175, we specified that we would publish a rule removing the waiver provisions from the regulations after the waiver expired. The waiver has expired and we are removing the provisions from the Medicare regulations.

##### **II. Waiver of Proposed Rulemaking and Delay of Effective Date**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on a proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the findings and its reasons in the rule issued.

Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay of the effective date. The purpose of the 30-day waiting period between publication of an administrative agency final rule and its effective date is to give affected parties reasonable time to adjust their behavior before the final rule takes place.

The state of emergency under which we granted a waiver of the ESRD conditions of coverage is now over in the Houston, Texas area, and Memorial Hermann Hospital is reopened to furnish kidney transplant services. We announced in the June 20, 2001 final rule our intention to remove the