emissions;'' and 445B.229, ''Hazardous emissions: Order for reduction or discontinuance.''

(*ii*) August 19, 2004, effective date September 24, 2004: 445B.001, ''Definitions;'' 445B.22043, ''Sulfur emissions: Exceptions for stationary sources;'' and 445B.2205, ''Sulfur emissions: Other processes which emit sulfur.''

(*iii*) October 4, 2005: 445B.063, ''Excess emissions defined;'' 445B.153, ''Regulated air pollutant defined;'' 445B.22017, ''Visible emissions: Maximum opacity; determination and monitoring of opacity;'' 445B.2202, ''Visible emissions: Exceptions for stationary sources;'' and 445B.22093, ''Organic solvents and other volatile compounds.''

(*iv*) March 8, 2006: 445B.275, ''Violations: Acts constituting; notice;'' and 445B.277, ''Stop orders.''

(*v*) September 6, 2006: 445B.220, ''Severability.''

* * * * *

[FR Doc. E8–7046 Filed 4–8–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0433; FRL–8357–5]

1-Methylcyclopropene; Amendment to an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an amendment to an exemption from the requirement of a tolerance for residues of the 1-Methylcyclopropene (1-MCP) on fruits and vegetables when applied or used outdoors for pre-harvest treatments. Agrofresh Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an amendment to the existing 1-MCP exemption from the requirement of a tolerance at 40 CFR 180.1220. This regulation eliminates the need to establish a maximum permissible level for residues of 1-Methylcyclopropene.

DATES: This regulation is effective April 9, 2008. Objections and requests for hearings must be received on or before June 9, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0433. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this ''**Federal Register**'' document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0433 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 June 9, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0433, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One

Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 8, 2007 (72 FR 44520) (FRL–8138–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7170) by Agrofresh, Inc., 100 Independence Mall, Philadelphia, PA 19106–2399. The petition requested that 40 CFR 180.1220 be amended to include residues resulting from outdoor pre-harvest use of 1-Methylcyclopropene. 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 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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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) of FFDCA 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.

1-Methylcyclopropene (1-MCP) is a plant regulator known for inhibiting ripening and aging of plants, flowers, fruits, and vegetables caused by the production of ethylene. 1-MCP acts by blocking the attachment of ethylene to tissue, and thus, prolonging the life of the food commodity treated. This mode of action is not relevant in animals, since ethylene receptors are not present in animal tissues.

The toxicity profile of 1-MCP has already been assessed by the Agency for its pesticidal use and in support of the tolerance exemption for post-harvest use in or on fruits and vegetables. The final rule was published on July 26, 2002 (67 FR 48796)(FRL–7187–4). Comprehensive review of studies submitted and risk assessment conducted on 1-MCP with regard to its toxicity to human health, done in support of the current petition and the approved tolerance exemption for post-harvest usage, have all concluded that this compound has a low acute toxicity.

1. *Acute toxicity*. 1-MCP exhibits low acute toxicity for all routes of exposure. It is a category IV for acute oral, dermal, inhalation, eye and dermal irritations. Moreover, 1-MCP is not a skin sensitizer, and no hypersensitivity incidents were observed following exposure to 1-MCP.

2. *Genotoxicity*. 1-MCP was not mutagenic when tested 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.

3. *Developmental toxicity*. 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 milligram active ingredient/Liter (mg a.i./L) (or 543 mg a.i./kilogram (kg)/day, 6 hour (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*. 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 request to waive the immune response from the testing guidelines. A scientific rationale based on the current toxicological data submitted on 1-MCP was provided to address this data requirement. 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, the Agency granted the request to waive immune response from the testing guidelines.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA 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*. The primary source for human exposure to 1-MCP will be from ingestion of raw and processed fruits and vegetables treated with 1-MCP before and after the harvest. Studies submitted, conducted in the field on apples (MRID 470886–12), maize (MRID 470886–11) and tomatoes (471082–03), showed residues in treated fruits to be extremely low. Moreover, harvested apples treated with 1-MCP in storage areas (MRID 456090–02), showed also low residue (average residue was 0.004 part per million (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*. No significant drinking water exposure and residues are expected to result from the pesticidal use of 1-MCP when applied or used as directed on the label and in accordance with good agricultural practices. Moreover, review of the study for soil absorption (OPPTS 835.1220), showed that the field use of 1-MCP should not result in leaching of 1-MCP residues to ground water.

B. Other Non-Occupational Exposure

There are no residential, school or day care uses proposed for this product. Since the proposed use pattern is for agricultural food crops, the potential for non-occupational, non-dietary exposures to 1-MCP by the general population, including infants and children, is highly unlikely.

1. *Dermal exposure*. Non-occupational dermal exposures to 1-MCP when used as a plant regulator are expected to be negligible because it is limited to agricultural use.

2. *Inhalation exposure*. Non-occupational inhalation exposures to 1-MCP when used as a plant regulator are expected to be negligible because it is limited to agricultural use.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish an exemption from 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.'' These considerations include the possible cumulative effects of such residues on infants and children.

EPA has considered the potential for cumulative effects of 1-MCP and other substances in relation to a common mechanism of toxicity. 1-MCP cannot share a common mechanism of toxicity with other substances because this compound is not toxic to mammalian systems. Thus, section 408(b)(2)(D)(v) does not apply.

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

A. 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, infants, and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of mammalian toxicity of 1-MCP and the already widespread exposure to 1-MCP when used on pre-harvested and post-harvested fruits and vegetable, without any reported adverse effects on human health. For these reasons, the Agency has determined that residues of 1-MCP from pre-harvest treatment of fruits and vegetables are safe, i.e., there is a reasonable certainty that no harm will result from aggregate exposure to such residues.

B. Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (also referred to as a margin of safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all available information, the Agency concludes that 1-MCP is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when 1-MCP is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure approach to assess the safety of 1-MCP.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of 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.''

1-MCP is not known as an endocrine disruptor nor is it related to any class of known endocrine disruptors. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this final rule for1-MCP.

B. Analytical Method

Through this action, the Agency proposes to establish an exemption from the requirement of a tolerance for 1-MCP when used on fruit and vegetable crops. For the very same reasons that support the granting of this tolerance exemption, the Agency has concluded that an analytical method is not required for enforcement purposes for these proposed uses of 1-MCP.

C. Codex Maximum Residue Level

There are no codex maximum residue levels established for 1-MCP.

VIII. Conclusions

The Agency does not expect any human health concerns from exposure to residues of 1-MCP when applied or used as directed on the label and in accordance with good agricultural practices. The data submitted by applicant and reviewed by the Agency support the petition for an exemption from the requirement of a tolerance, for 1-MCP on pre-harvested fruits and vegetable, when the product is applied or used as directed on the label.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under

Executive Order 12866, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 31, 2008.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1220 is revised 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 the 1-Methylcyclopropene in or on fruits and vegetables when:

(a) Used as a post harvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene.

(b) Applied or used outdoors for pre-harvest treatments.

[FR Doc. E8–7458 Filed 4–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0303; FRL–8357–2]

Fenhexamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fenhexamid in or on asparagus. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 9, 2008. Objections and requests for hearings must be received on or before June 9, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0303. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are