health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g). A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T17–020 is added to read as follows:

§ 165.T17–020 Port Valdez and Valdez Narrows, Valdez, Alaska-security zones.

(a) *Location.* The following areas are security zones—

(1) *Trans-Alaska Pipeline System (TAPS) Valdez Terminal Complex (Terminal), Valdez, Alaska.* All waters enclosed within a line beginning on the southern shoreline of Port Valdez at 61°04.97′ N, 146°26.33′ W; thence northerly to the yellow buoy at 61°06.50′ N, 146°26.33′ W; thence east to the yellow buoy at 61°06.50′ N, 146°21.23′ W; thence south to 61°05.11′ N, 146°21.23′ W; thence west along the shoreline and including the area 2000 yards inland along the shoreline to the beginning point. This security zone encompasses all waters approximately 1 mile north, east and west of the TAPS Terminal between Allison Creek (61°05.11′ N, 146°21.23′ W) and Sawmill Spit (61°04.97′ N, 146°26.33′ W).

(2) *Tank Vessels in COTP Prince William Sound Zone.* All waters within 200 yards of any tank vessel maneuvering to approach, moor, unmoor or depart the TAPS Terminal or transiting, maneuvering, laying to, or anchored within the boundaries of the Captain of the Port, Prince William Sound Zone described in 33 CFR 3.85–20(b).

(3) *Valdez Narrows, Port Valdez, Valdez, Alaska.* All waters within 200 yards of the Valdez Narrows Tanker Optimum Track line, when a tanker is navigating through the narrows.

(i) The Valdez Narrows Tanker Optimum Track line is a line commencing at 61°05.38′ N, 146°37.38′ W; thence south westerly to 61°04.05′ N, 146°40.05′ W; thence southerly to 61°04.05′ N, 146°41.20′ W.

(ii) This security zone encompasses all waters 200 yards either side of the Valdez Narrows Optimum Track line.

(iii) Whenever a tank vessel is navigating on the Valdez Narrows Optimum Track line, the security zone is activated and subject to enforcement. All vessels forward of a TAPS tanker's movement shall vacate the security zone surrounding the Optimum Track line. Vessels may reenter the security zone astern of a moving tanker provided that a 200 yards separation is given, as required in paragraph (a)(2) of this section.

(b) *Regulations.* (1) The general regulations in 33 CFR 165.33 apply to the security zones established in paragraph (a) of this section. No person or vessel may enter these security zones without permission of the Captain of the Port, Prince William Sound.

(2) All persons and vessels granted permission to enter these security zones must comply with the instructions of the Captain of the Port representative or designated on-scene patrol vessel. These personnel are comprised of commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel must proceed as directed.

(3) The Captain of the Port or his representative or the designated on-scene patrol vessel may authorize vessels to enter the security zones in this section.

(c) *Effective period.* This section is effective from June 13, 2005, to October 11, 2005.

Dated: June 10, 2005.

M.S. Gardiner,

Commander, U.S. Coast Guard, Captain of the Port, Prince William Sound.

[FR Doc. 05–12932 Filed 6–29–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0119; FRL–7718–3]

Cyprodinil; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes time-limited tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine in or on onion, dry bulb; onion, green; and strawberry. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). These tolerances will expire on December 31, 2007.

DATES: This regulation is effective June 30, 2005. Objections and requests for hearings must be received on or before August 29, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0119. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions discussed above. 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 and Other Related Information?

In addition to using EDOCKET*(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of January 7, 2005 (70 FR 1435) (FRL–7694–3), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E5012) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.532 be amended by extending the time-limited tolerances to December 31, 2007, for residues of the fungicide, cyprodinil, 4-cyclopropyl-6- methyl-N-phenyl-2-pyrimidinamine in or on the raw agricultural commodities onion, dry bulb at 0.60 part per million (ppm); onion, green at 4.0 ppm; and strawberry at 5.0 ppm. This notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. Comments were received from one individual opposing and objecting to the establishment of tolerances for residues of cyprodinil. The individual criticized IR-4's involvement in the pesticide registration as well as EPA's way of conducting pesticide registration. EPA's response to the public comments received is in Unit V. of this document. The tolerances will expire on December 31, 2007.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the 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. Section 408(b)(2)(C) of the FFDCA 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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of cyprodinil on onion, dry bulb at 0.60 ppm; onion, green at 4.0 ppm; and strawberry at 5.0 ppm.

In the **Federal Register** of September 23, 2003 (68 FR 54808, FRL–7326–4) the Agency published a Final rule establishing tolerances for residues of cyprodinil in or on brassica, head and stem, subgroup 5A; brassica, leafy

greens, subgroup 5B; carrot; herb, subgroup 19A, dried; herb, subgroup 19A, fresh; longan; lychee; pulasan; rambutan; Spanish lime; and turnip, greens. When the Agency conducted the risk assessments in support of this tolerance action it assumed that cyprodinil residues would be present on dry bulb onion, green onion and strawberry as well as on all foods covered by the proposed and established tolerances. Residues on dry bulb onion, green onion and strawberry were included because there were existing time-limited tolerances for these commodities. Therefore, re-establishing the dry bulb onion, green onion and strawberry tolerances will not change the most recent estimated aggregate risks resulting from use of cyprodinil, as discussed in the September 19, 2003 **Federal Register** (68 FR 54808, FRL–7326–4). Refer to the September 19, 2003 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the estimated aggregate risks from potential exposures to cyprodinil.

Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure. An acute Population Adjusted Dose (aPAD) of 1.5 mg/kg/day has been identified for females 13–49 years.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An unrefined, Tier 1 acute dietary exposure assessment (using tolerance-level residues, DEEM™ (version 7.76) default processing factors and assuming 100% crop treated for all proposed commodities) was conducted for the females 13–49 years old population subgroup.

The acute dietary exposure from food to cyprodinil will occupy 2% of the aPAD for the females 13–49 years old. In addition, there is potential for acute dietary exposure to cyprodinil in drinking water. After calculating drinking water levels of comparison (DWLOCs) and comparing them to the estimated environmental concentrations (EECs) for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYPRODINIL

Population Subgroup/	aPAD (mg/kg)	% aPAD/(Food)	Surface Water EEC/(ppb)	Ground Water EEC/(ppb)	Acute DWLOC/(ppb)
Females 13–49 years old	1.5	2	32.9	0.16	44,000

A chronic Population Adjusted Dose (cPAD) of 0.03 mg/kg/day has been identified for all population subgroups. In conducting the chronic dietary risk assessment EPA used DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessment: An unrefined, Tier 1 chronic dietary exposure assessment (using tolerance-level residues, DEEM default processing factors, and assuming 100% crop treated for all proposed commodities) was conducted for the general U.S. population and various population subgroups.

EPA has concluded that exposure to cyprodinil from food will utilize 25% of the cPAD for the U.S. population, 65% of the cPAD for (the most highly exposed population subgroup) children 1–2 years old, 32% of the cPAD for all infants <1 year old, and 21% of the cPAD for females 13–49 years old. Cyprodinil is not registered for use on any sites that would result in residential exposure. In addition, there is potential for chronic dietary exposure to cyprodinil in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2. AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYPRODINIL

Population/Subgroup	cPAD/mg/kg/day	%/cPAD/(Food)	Surface Water EEC/(ppb)	Ground/Water EEC/(ppb)	Chronic/DWLOC (ppb)
U.S. Population	0.03	25	8.1	0.16	790
All infants < 1 year old	0.03	32	8.1	0.16	200
Children 1 – 2 years old	0.03	65	8.1	0.16	100
Females 13 – 49 years old	0.03	21	8.1	0.16	710

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to cyprodinil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The results of Multiresidue Method testing of cyprodinil and its metabolite CGA-232449 have been forwarded to the Food and Drug Administration (FDA). Cyprodinil was tested according to the FDA Multiresidue protocols (Protocols C, D, and E), and acceptable recoveries were obtained for cyprodinil fortified in apples at 0.50 ppm using Protocol D. The petitioner is proposing the Method AG-631A as a tolerance enforcement method for residues of cyprodinil in/on the subject crops. The method includes confirmatory procedures using gas chromatography/nitrogen/phosphorus detector (GC/NPD). The method has successfully undergone radiovalidation using 14C-labeled tomato samples and independent laboraory validation. In addition, the method has been the subject of acceptable Agency petition method validations on stone fruits and almond nutmeat and hulls. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of cyprodinil in/on the proposed crops. Therefore, harmonization is not an issue.

V. EPA's Response to Public Comments Received Regarding the Notice of Filing

Comments were received from one individual opposing and objecting to the extension of tolerances for residues of cyprodinil. The individual criticized IR-4's involvement in the pesticide registration as well as EPA's way of conducting pesticide registration. The comments were in response to the notice of filing published in the **Federal Register** of January 7, 2005 (70 FR 1435) (FRL–7694–3). The communication objected to extension of the proposed tolerances for several reasons and mostly involved generalized and unsubstantiated disagreement with EPA's risk assessment methodologies or safety findings. Each comment is listed below, followed by the Agency response.

One comment indicated that IR-4 and Rutgers University are pushing more toxics upon this nation. Agency response: Although the concerns regarding IR-4 and Rutgers University to seek pesticide tolerances and registrations are not germane to EPA's statutory basis for acting on the cyprodinil tolerance petition, and thus technically no response is required to this comment, EPA can provide the following information regarding the Interregional Research Project Number 4 (IR-4). The IR-4 program was created by Congress in 1963 in order to assist minor crop growers in the process of obtaining pesticide registrations. IR-4 National Coordinating Headquarters is located at Rutgers University in New Jersey and receives the majority (90%) of its funding from the USDA. It is the only publicly funded program that conducts research and submits petitions for tolerances. IR-4 operates in collaboration with USDA, the Land Grant University System, the agrochemical industry, commodity associations, and EPA. IR-4 identifies needs, prioritizes accordingly, and conducts research. The majority (over 80%) of IR-4's research is conducted on reduced-risk chemicals. In addition to the work done in pesticide registration, IR-4 develops risk mitigation measures for existing registered products.

Another comment noted that 8.4% of the chronic reference dose (RfD) for children 1 to 2 year old is contemplated and that this was done for profiteering and will harm children. Agency Response: For dietary risk assessment (other than cancer) a chronic RfD represents the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment with an uncertainty factor (UF) applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. For cyprodinil an UF of 100 was used, 10X to account for interspecies differences and 10X for intraspecies differences (RfD = NOAEL/UF). Given the use of a NOAEL and UF to calculate the chronic RfD the Agency feels that estimated exposures less than 100% of the chronic RfD will be protective of the general population, and to infants and children.

An additional comment indicated that the standard for a ''reasonable certainty'' is simply not a high enough standard. Agency Response: Under the existing legal framework provided by section 408 of the FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the 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.''

A final comment stated that this chemical should not be allowed to be sold until the Agency has determined if cyprodinil has a common mechanism of toxicity with other pesticides. Agency response: The comment applied to the use of ''available data'' concerning the cumulative effects of the pesticide's residues and ''other substances that have a common mechanism of toxicity.'' In this case, EPA did not assume that this chemical has a common mechanism of toxicity with other substances as the chemical does not generate metabolites produced also by other chemicals. For specific information regarding EPA's approach to the use of common mechanism of toxicity to evaluate the cumulative effects of chemicals, please refer to EPA's website at *http://www.epa.gov/pesticides/cumulative/* to see policy statements.

In conclusion, the comments contained no scientific data or other substantive evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to cyprodinil from the re-establishment of these tolerances.

VI. Conclusion

Therefore, these tolerances are re-established for residues of cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, in or on onion, dry bulb at 0.60 ppm, onion, green at 4.0 ppm, and strawberry at 5.0 ppm.

VII. 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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 sections 408 and 409 of the FFDCA. 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–2005–0119 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 August 29, 2005.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0119, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 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).

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 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 section 408(d) of the 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. 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 section 408(n)(4) of the FFDCA. 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.

IX. Congressional Review Act

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: June 21, 2005.

Lois Rossi,

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), 346a and 371.

§ 180.532 [Amended]

■ 2. In § 180.532, in the table to paragraph (a)(2), amend the entries for ''Onion, dry bulb''; ''Onion, green''; and ''Strawberry'' by revising the expiration date ''12/31/04'' to read ''12/31/07.''

[FR Doc. 05–12921 Filed 6–29–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0153; FRL–7717–1]

Ethyl Maltol; 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 2-ethyl-3-hydroxy- 4H-pyran-4-one, also known as ethyl maltol when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Firmenich Incorporated 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 exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethyl maltol.

DATES: This regulation is effective June 30, 2005. Objections and requests for hearings must be received on or before August 29, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0153. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address: *campbell.princess@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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of December 20, 2000 (65 FR 79834) (FRL–6751–9), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6E4758) by Firmenich Incorporated, P.O. 5880, Princeton, NJ 08543. The petition requested that 40 CFR 180.1001(c) and (e), re-designated as 40 CFR 180.910 and 40 CFR 180.930, respectively (69 FR 23113, April 28, 2004 (FRL–7335–4)), be