a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practices and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 24, 1999.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, 40 CFR Part 63 is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Section 63.42(b) is revised to read as follows:

§ 63.42 Program requirements governing construction or reconstruction of major sources.

* * * * *

(b) *Failure to adopt program.* In the event that the permitting authority fails to adopt a program to implement section 112(g) with respect to construction or reconstruction of major sources of HAP with an effective date on or before June 29, 1998, and the permitting authority concludes that it is able to make case-by-case MACT determinations which conform to the provisions of § 63.43 in the absence of such a program, the permitting authority may elect to make such determinations. However, in those instances where the permitting authority elects to make case-by-case MACT determinations in the absence of a program to implement section 112(g) with respect to construction or reconstruction of major sources of HAP, no such case-by-case MACT determination shall take effect until after it has been submitted by the permitting authority in writing to the appropriate EPA Regional Adminstrator and the EPA Regional Administrator has concurred in writing that the case-by-case MACT determination by the permitting authority is in conformity with all requirements established by §§ 63.40 through 63.44. In the event that the permitting authority fails to adopt a program to implement section 112(g) with respect to construction or reconstruction of major sources of HAP with an effective date on or before June 29, 1998, and the permitting authority concludes that it is unable to make case-by-case MACT determinations in the absence of such a program, the permitting authority may request that the EPA Regional Administrator implement a transitional program to implement section 112(g) with respect to construction or reconstruction of major sources of HAP in the affected State of local jurisdiction while the permitting authority completes development and adoption of a section 112(g) program. Any such transitional section 112(g) program implemented by the EPA Regional Administrator shall conform to all requirements established by §§ 63.40 through 63.44, and shall remain in effect for no more than 30 months. Continued failure by the permitting authority to adopt a program to implement section 112(g) with respect to construction or reconstruction of major sources of HAP shall be construed as a failure by the permitting authority to adequately administer and enforce its title V permitting program and shall constitute cause by EPA to apply the sanctions and remedies set forth in the Clean Air Act section 502(I).

* * * * *

[FR Doc. 99–16681 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300876; FRL–6086–3]

RIN 2070–AB78

Cyprodinil; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of cyprodinil in or on caneberries. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on caneberries. This regulation establishes a maximum permissible level for residues of cyprodinil in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective June 30, 1999. Objections and requests for hearings must be received by EPA on or before August 30, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300876], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300876], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300876]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 271, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9362, schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide cyprodinil, in or on caneberries at 10 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked

tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New 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) 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Cyprodinil on Caneberries and FFDCA Tolerances

According to the Applicants, weather conditions favorable to gray mold disease development, combined with pathogen resistance to existing registered fungicides, has contributed to an emergency condition for caneberry growers in the States of Washington and Oregon. The States claim that registered pesticides either do not provide an adequate level of economic control of gray mold fruit rot or are limited in the number of applications needed for season-long control. EPA has authorized under FIFRA section 18 the use of the product Switch 62.5 WG, containing the active ingredients cyprodinil and fludioxonil, on caneberries for control of gray mold in Oregon and Washington. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cyprodinil in or on caneberries. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on caneberries after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether cyprodinil meets EPA's registration requirements for use on caneberries or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of cyprodinil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any States other than Oregon and Washington to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for cyprodinil, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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 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).

Consistent with section 408(b)(2)(D), 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 cyprodinil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of cyprodinil on caneberries at 10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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 nature of the toxic effects caused by cyprodinil are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

2. *Short - and intermediate-term toxicity.* A no observed adverse effect level (NOAEL) of 25 milligrams/kilograms/day (mg/kg/day) was selected from the 21–day dermal rat study. The effect observed at the lowest observed adverse effect level (LOAEL) of 125 mg/kg/day in this study was hunched posture in females.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for cyprodinil at 0.03 mg/kg/day. This RfD is based on a NOAEL of 2.7 mg/kg/day and an uncertainty factor of 100. The NOAEL was taken from the chronic rat study; at the LOAEL of 35.6 mg/kg/day, effects observed were histopathological alterations in the liver (*spongiosis hepatis*) in males.

4. *Carcinogenicity*. Cyprodinil is classified as a ''not likely'' human carcinogen, based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.532) for the residues of cyprodinil, in or on a variety of raw agricultural commodities. Mention any tolerances of special relevance and meat, milk, poultry and egg tolerances, if applicable. Risk assessments were conducted by EPA to assess dietary exposures and risks from cyprodinil as follows:

i. *Acute exposure and risk.* 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 1–day or single exposure. This risk assessment is not required. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

ii. *Chronic exposure and risk.* Tolerance level residues and 100% crop treated were assumed to calculate dietary exposure for the United States (U.S.) population and population subgroups from residues on published and proposed uses. Chronic exposure from food uses of cyprodinil represents 6% of the RfD for the U.S. population and 21% of the RfD for nursing infants (<1yr), the subgroup most highly exposed.

2. *From drinking water.* Cyprodinil is considered to be persistent in water and mobile in most soils; under most conditions though, cyprodinil will have a low potential for movement into ground water at high concentrations. There is potential for cyprodinil to contaminate surface water as runoff and as a sorbed species through erosion of soil particles. There is no established Maximum Contaminant Level (MCL) for residues of cyprodinil in drinking water. No health advisory levels for cyprodinil in drinking water have been established.

The Agency has calculated drinking water levels of comparison (DWLOCs) for chronic exposure to cyprodinil in surface and ground water. A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. Toxicity endpoints, default body weight (70 kg for males, 60 kg for females, and 10 kg for nursing infants < 1 year old) and default drinking water consumption estimates (2 liter (L)/day for adults, 1 L/day for nursing infants) are used to calculate the actual DWLOCs. The DWLOC represents the concentration level in surface water or ground water at which aggregate exposure to the chemical is not of concern.

Using the Screening Concentration in Ground Water (SCI-GROW) screening model, the Agency calculated an Estimated Environmental Concentration (EEC) of cyprodinil in ground water for use in human health risk assessments. This value represents an upper bound estimate of the concentration of cyprodinil that might be found in ground water assuming the maximum application rate allowed on the label of the highest use pattern.

The Agency used its Pesticide Root Zone Model (PRZM)-EXAMS model to estimate EECs for cyprodinil in surface water. PRZM-EXAMS is a more refined Tier II assessment. The EECs from these models are compared to the DWLOCs to make the safety determination.

i. *Acute exposure and risk.* This risk assessment is not required. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

ii. *Chronic exposure and risk.* Using the SCI-GROW model, the maximum long-term estimated concentration in ground water is not expected to exceed 0.04 parts per billion (ppb). The chronic estimated concentration in surface water, using the PRZM-EXAMS model, is 51 ppb. The DWLOC for the U.S. population was calculated to be 990 ppb; the DWLOC for the most sensitive subgroup, nursing infants < 1 year old, was 220 ppb. As concentrations of cyprodinil in ground water and surface water do not exceed the calculated DWLOCs, the Agency concludes with reasonable certainty that chronic exposure to cyprodinil in drinking water is not of concern.

3. *From non-dietary exposure.* Cyprodinil is currently not registered for use on residential, non-food sites; therefore, no non-occupational, non-dietary exposure is expected.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether cyprodinil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyprodinil has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* This risk assessment is not required. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

2. *Chronic risk.* Using the Theoreticl Maximus Residue Contribution (TMRC) exposure assumptions described in this unit, EPA has concluded that aggregate

exposure to cyprodinil from food will utilize 6 of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is nursing infants < 1 year old (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Estimated chronic environmental concentrations of cyprodinil in surface water and ground water do not exceed chronic DWLOCs calculated by the Agency; therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

There are no residential uses of this chemical registered. This risk assessment is therefore not required.

4. *Aggregate cancer risk for U.S. population*. Cyprodinil is classified as a ''not likely'' human carcinogen, based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential. This risk assessment is not required.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyprodinil residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* — i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of cyprodinil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the rat developmental study, the maternal NOAEL was 200 mg/kg/day, based on decreased body weight, body weight gain, and food consumption at the LOAEL of 1,000 mg/kg/day. The developmental NOAEL was 200 mg/kg/day, based on increased incidence of skeletal variations (primarily absent or reduced ossification of the metacarpal) and on decreased mean fetal weight at the LOAEL of 1,000 mg/kg/day. In the rabbit developmental toxicity study, the maternal NOAEL was 150 mg/kg/day, based on decreased body weight gain at the LOAEL of 400 mg/kg/day. The developmental NOAEL was 150 mg/kg/day and the LOAEL was 400 mg/kg/day, based on increased incidence of 13th rib.

iii. *Reproductive toxicity study*. In the 2–generation reproductive toxicity study in rats, the parental NOAEL was 81 mg/kg/day, based on decreased parental female premating body weight gain at the LOAEL of 326 mg/kg/day. The Agency considers significant increases in kidney and liver weight at the 326 mg/kg/day dose as supportive evidence of toxicity. The reproductive/developmental NOAEL was 81 mg/kg/day and the LOAEL was 326 mg/kg/day, based on decreased F_1 and F_2 pup weight during lactation and continuing into adulthood for F_1 rats.

iv. *Pre- and postnatal sensitivity*. The toxicological data base for evaluating pre- and postnatal toxicity for cyprodinil is complete with respect to current data requirements. There are no pre- or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2–generation rat reproductive toxicity study.

v. *Conclusion*. There is a complete toxicity data base for cyprodinil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency determined that for cyprodinil, the 10x factor to account for enhanced sensitivity of infants and children should be removed.

2. *Acute risk*. This risk assessment is not required. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to cyprodinil from food will utilize 21 of the RfD for nursing infants < 1 year old, the infant and children subgroup most highly exposed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Because the chronic DWLOCs are not exceeded by estimated chronic environmental concentrations in ground water or surface water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. There are no residential uses for this chemical; this risk assessment is not required.

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

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plant is understood based on metabolism studies in stone fruit, pome fruit, wheat, tomatoes and potatoes. The residue of concern is parent cyprodinil only. There are no animal feed items associated with the proposed use; data on the nature of the residue in animals are not required for the section 18 action or the establishment of this tolerance.

B. Analytical Enforcement Methodology

Adequate enforcement methodology High Performance Liquid Chromotography (HPLC) is available to enforce the tolerance expression; OPP concludes that the method will be suitable for enforcement purposes once revisions recommended by the Analytical Chemistry Laboratory (ACL) are incorporated. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection

Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Residues of cyprodinil are not expected to exceed 10 ppm in caneberries as a result of the proposed section 18 use.

D. International Residue Limits

There are no Codex, Canadian, or Mexican residue limits established for cyprodinil on caneberries. Therefore, no compatibility problems exist for the proposed tolerance.

E. Rotational Crop Restrictions

As caneberries are not considered to be a rotated crop, no rotational crop data are required.

V. Conclusion

Therefore, the tolerance is established for residues of cyprodinil in caneberries at 10 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 30, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300876] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding

exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. 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 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 the rule in the **Federal Register**. This 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 11, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.532, by alphabetically adding the commodity ''caneberries'' to the table in paragraph (b) to read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Caneberries	10	12/31/00

* * * * *

[FR Doc. 99–16542 Filed 6–29–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300877; FRL–6086–4]

RIN 2070–AB78

Fludioxonil; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fludioxonil in or on caneberries. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on caneberries. This regulation establishes a maximum permissible level for residues of fludioxonil in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective June 30, 1999. Objections and requests for hearings must be received by EPA on or before August 30, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300877], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests