ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300832; FRL–6073–1]

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 strawberries. 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 strawberries. 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 May 31, 2000.

DATES: This regulation is effective April 21, 1999. Objections and requests for hearings must be received by EPA on or before June 21, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300832], 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–300832], 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–300832]. 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 sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for residues of the fungicide fludioxonil, in or on strawberries at 2.0 part per million (ppm). This tolerance will expire and is revoked on May 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) (Pub. L. 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 preeamble 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 Fludioxonil on Strawberries and FFDCA Tolerances

According to the Applicant, gray mold caused by *Botrytis cinerea* is one of the most severe problems limiting strawberry production in Florida. Gray mold affects both flowers and fruit, resulting in marketable yield losses. Historically, gray mold has been controlled with bloom sprays of Rovral (iprodione) then weekly applications of captan until harvest. This schedule has provided good control of gray mold, especially for relatively resistant varieties, such as Oso Grande.

However, a shift toward the usage of certain varieties of strawberries which have specific desirable attributes (i.e.,

production, pest resistance or tolerance, etc.) but are more susceptible to gray mold, the development of gray mold strains with resistance to iprodione, and limitation of iprodione use on strawberries recently instituted as part of the iprodione reregistration has resulted in a situation where growers expect heavy losses without the requested product, Switch (which contains the active ingredients cyprodinil and fludioxonil). EPA has authorized under FIFRA section 18 the use of fludioxonil on strawberries for control of gray mold in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fludioxonil in or on strawberries. 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 May 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 strawberries after that date will not be unlawful, provided the pesticide is applied at a time and 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 fludioxonil meets EPA's registration requirements for use on strawberries 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 fludioxonil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Florida 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 fludioxonil, 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 fludioxonil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fludioxonil on strawberries at 2.0 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 fludioxonil are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. No endpoint was identified for acute dietary exposure. The Agency has concluded that the toxicology database does not suggest the need for this assessment.

2. *Short- and intermediate-term toxicity*. No toxicological endpoints of concern were identified for acute oral exposure, short-term dermal exposure or inhalation exposure for all time periods. Risk assessments for these exposure scenarios were not conducted.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for fludioxonil at 0.03 milligrams/kilogram/day (mg/kg/day). This RfD is based on a no observed adverse effects level (NOAEL) of 3.3 mg/kg/day, taken from a chronic feeding study in dogs, and an uncertainty factor of 100. The effect observed at the lowest effect level (LEL) of 35.5 mg/kg/day was decreased body weight gain in females.

4. *Carcinogenicity*. Fludioxonil has been classified as a Group D- not classifiable as to human carcinogenicity-chemical by the Cancer Peer Review Committee. The Group D classification was based on the statistically significant increase in liver tumors in female rats for combined adenoma/carcinoma only, the lack of a tumorigenic response in male rats or in either sex of the mouse, and the need for additional mutagenicity studies.

C. Exposures and Risks

1. *From food and feed uses*. A tolerance has been established (40 CFR 180.516) for the residues of fludioxonil, in or on potatoes at 0.02 ppm. Fludioxonil is currently registered for use as a seed treatment on potatoes, popcorn, field and sweet corn, and sorghum, as well as for use in greenhouses on nonfood crops. Additionally, time-limited tolerances have been established for residues of fludioxonil on apricots, nectarines, peaches and plums. Risk assessments were conducted by EPA to assess dietary exposures and risks from fludioxonil 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. In reviewing the toxicity data base, no toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore a risk assessment for this exposure scenario is not required.

ii. *Chronic exposure and risk*. Tolerance level residues and 100% crop treated were assumed to calculate theoretical maximum residue contribution (TMRCs) for the United States (U.S.) population and population subgroups from residues on published and proposed uses. Chronic exposure from food uses of fludioxonil represents 4% of the RfD for the U.S. population and 22% of the RfD for non-nursing infants (<1yr), the subgroup most highly exposed.

2. *From drinking water*. Fludioxonil is not expected to impact ground or surface water resources. Available data suggest fludioxonil has a relatively low potential to leach to groundwater and move in runoff to aquatic environments. There is no established Maximum Contaminant Level (MCL) for residues of fludioxonil in drinking water. No

health advisory levels for fludioxonil in drinking water have been established.

The Agency has calculated drinking water levels of comparison (DWLOCs) for chronic exposure to fludioxonil in surface and groundwater. The DWLOCs are calculated by subtracting from the RfD the respective chronic dietary exposure attributable to food to obtain the acceptable exposure to fludioxonil in drinking water. Default body weight (70 kg for males, 60 kg for females, and 10 kg for non-nursing infants < 1 year old) and default drinking water consumption estimates (2 L/day for adults, 1 L/day for non-nursing infants) are then used to calculate the actual DWLOCs. The DWLOC represents the concentration level in surface water or groundwater at which aggregate exposure to the chemical is not of concern.

Using Generic expected environmental concentration (GENEEC) (surface water) and Screening Concentration in GROund Water(SCI-GROW) (groundwater) models, the Agency has calculated chronic Tier I Estimated Environmental Concentrations (EECs) for fludioxonil for use in human health risk assessments. These values represent the upper bound estimates of the concentrations of fludioxonil that might be found in surface and ground water assuming the maximum application rate allowed on the label of the highest use pattern. The EECs from these models are compared to the DWLOCs to make the safety determination.

i. *Acute exposure and risk*. In reviewing the toxicity data base, no toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore a risk assessment for this exposure scenario was not conducted.

ii. *Chronic exposure and risk*. Using the SCI-GROW model, the maximum long-term estimated concentration in groundwater is not expected to exceed 0.08 parts per billion (ppb). The chronic estimated concentration in surface water, using the GENEEC model, is 7.8 ppb. The DWLOC for the most sensitive adult subgroup, non-Hispanic females other than black or white was calculated to be 850 ppb; DWLOCs for all other adult population groups are even higher. As even the upper bound concentrations of fludioxonil in groundwater and surface water are not expected to exceed the calculated DWLOC, the Agency concludes with reasonable certainty that chronic exposure to fludioxonil in drinking water is not of concern.

3. *From non-dietary exposure*. Fludioxonil is currently not registered for use on non-food sites that would result in non-occupational, non-dietary exposure; therefore, no such exposure is expected.

4. *Cumulative exposure to substances with 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 fludioxonil 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, fludioxonil 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 fludioxonil 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*. In reviewing the toxicity data base, no toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore a risk assessment for this exposure scenario was not conducted.

2. *Chronic risk*. Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fludioxonil from food will utilize 4% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year in age (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 fludioxonil in surface water and groundwater do not exceed chronic DWLOCs calculated by the Agency. 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.

No toxicological endpoints of concern were identified for acute oral exposure, short-term dermal exposure or inhalation exposure for all time periods. Risk assessments for these exposure scenarios were not conducted.

4. *Aggregate cancer risk for U.S. population*. Fludioxonil has been classified as a Group D- not classifiable as to human carcinogenicity- chemical by the Cancer Peer Review Committee. The Group D classification was based on the statistically significant increase in liver tumors in female rats for combined adenoma/carcinoma only, the lack of a tumorigenic response in male rats or in either sex of the mouse, and the need for additional mutagenicity studies.

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 fludioxonil 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 fludioxonil, 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 post-natal toxicity and the completeness of the database 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 (systemic) NOAEL was 100 mg/kg/day, based on reduction in mean body weight gain in dams during gestation period at the lowest observed effects level (LOEL) of 1,000 mg/kg/day. The developmental (fetal) NOAEL was 100 mg/kg/day, based on increased fetal and litter incidence of dilated renal pelvis and dilated ureter at the LOEL of 1,000 mg/kg/day. In the rabbit developmental toxicity study, the maternal (systemic) NOAEL was 10 mg/kg/day, based on decreased body weight gains and food efficiency at the LOEL of 100 mg/kg/day. The developmental (pup) NOAEL was 300 mg/kg/day, the highest dose tested.

iii. *Reproductive toxicity study*. In the 2–generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 22.13 mg/kg/day (males) and 24.24 mg/kg/day (females), based on clinical signs and decreased body weight, body weight gain and food consumption at the LOEL of 221.6 mg/kg/day (males) and 249.7 mg/kg/day (females). The reproductive/developmental (pup) NOAEL was 22.13 mg/kg/day (males) and 24.24 mg/kg/day (females), based on reduced pup weights at the LOEL of 221.6 mg/kg/day (males) and 249.7 mg/kg/day (females).

iv. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for fludioxonil is complete with respect to current data requirements. There are no pre- or post-natal 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 database for fludioxonil and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. In reviewing the toxicity data base, no toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore a risk assessment for this exposure scenario was not conducted.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fludioxonil from food will utilize 22% of the RfD for non-nursing infants less than one, the subgroups 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 groundwater or surface water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *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.

No toxicological endpoints of concern were identified for acute oral exposure, short-term dermal exposure or inhalation exposure for all time periods. Risk assessments for these exposure scenarios were not conducted.

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 fludioxonil residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood based on a metabolism study submitted for seed treatment use on potatoes. The residue of concern is the parent compound, fludioxonil, only. There are no livestock feed items associated with the proposed use on strawberries. Therefore, the nature of the residue in animals is not germane to these section 18 requests or to the establishment of this tolerance.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (GC/NPD) is available to enforce the tolerance expression. 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 fludioxonil are not expected to exceed 2.0 ppm in/on strawberries as a result of the proposed section 18 use. Secondary residues are not expected in animal commodities as there are no feed items associated with the strawberry use.

D. International Residue Limits

There are no Codex residue limits established for fludioxonil, and no Canadian or Mexican residue limits for fludioxonil use on strawberries.

E. Rotational Crop Restrictions

No crops may be planted for at least 30 days following the last application of fludioxonil. The crop rotation restriction for cyprodinil, the other active ingredient in Switch 62.5 WG, prohibits planting any crop other than strawberries.

V. Conclusion

Therefore, the tolerance is established for residues of fludioxonil in strawberries at 2.0 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 June 21, 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–300832] (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) (Pub. L. 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: April 2, 1999.

Donald Stubbs,

Acting 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. Section 180.516, is amended by alphabetically adding the following commodity to the table in paragraph (b) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* *	* * *	
Strawberry	2.0	5/31/00

* * * * *

[FR Doc. 99–9709 Filed 4–20–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300836; FRL–6074–4]

RIN 2070–AB78

Dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide (monocrotophos) Final rule; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule announces the revocation of tolerances for Dimethyl phosphate of 3-hydroxy-*N*-methyl-*cis*-crotonamide (monocrotophos) for residues of sugarcane, potatoes, cotton seed, peanuts, peanut hulls, and tomatoes. The regulatory actions in this document are part of the Agency's reregistration program under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA).

By law, EPA is required to reassess 33% of the tolerances in existence on August 2, 1996, by August 1999, or about 3,200 tolerances. The regulatory actions indicated in this document pertain to the final revocation of tolerances and/or exemptions, which count toward the August, 1999, review deadline of FFDCA section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation becomes effective April 21, 1999. Objections and requests for hearings must be received on or before July 20, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IV of the SUPPLEMENTARY INFORMATION section of this notice. Be sure to identify the appropriate docket number [OPP–300836], which is an addendum to a previous docket.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Jamil Mixon, Reregistration Branch I, mail code (7508C), Special Review and Reregistration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location: Reregistration Branch I, CM #2, 6th floor, 1921 Jefferson Davis Hwy., Arlington, VA. Telephone: (703) 308–8032; e-mail: mixon.jamil @epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Notice Apply to Me?

You may be affected by this notice if you sell, distribute, manufacture, or use pesticides for agricultural applications, process food, distribute or sell food, or implement governmental pesticide regulations. Pesticide reregistration and other actions [see FIFRA section 4(g)(2)] include tolerance and exemption reassessment under FFDCA section 408. In this notice, the tolerance actions are proposed in coordination with the cancellation of associated registrations. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Agricultural Stakeholders.	Growers/Agricultural Workers Contractors [Certified/ Commercial Applicators, Handlers, Advisors, etc.] Commercial Processors Pesticide Manufacturers User Groups Food Consumers
Food Distributors	Wholesale Contractors Retail Vendors Commercial Traders/Importers
Intergovernmental Stakeholders.	State, Local, and/or Tribal Government Agencies
Foreign Entities	Governments, Growers, Trade Groups

This table 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 table could also be affected. If you have any questions regarding the applicability of this action to a particular entity, you can consult with the technical person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.