

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.

VII. 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: September 11, 2006.

James J. Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.624 is added to subpart C to read as follows:

§ 180.624 Metrafenone, tolerances for residues.

(a) *General.* Tolerances are established for residues of metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on the following commodities.

Commodity	Parts per million
Grape	0.6 ¹

¹ There is no U.S. registration on grapes as of September 20, 2006.

(b) *Section 18 emergency exemption.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0623; FRL-8090-5]

Dithianon; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of dithianon, (5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile in or on imported fruit, pome, group 11, and hop, dried cones. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 20, 2006. Objections and requests for hearings must be received on or before November 20, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0623. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Rose Mary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5611; e-mail address: kearns.rosemary@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. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0623, 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 November 20, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0623, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 12, 2006 (71 FR 19733) (FRL-7767-7), EPA issued a notice pursuant to section

408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E4781) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, N.C. 22709. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide dithianon, 5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile, in or on imported fruit, pome, group 11 at 5 parts per million (ppm) and hop, dried cones at 100 ppm. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of 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 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 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 <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of dithianon on fruit, pome, group 11 at 5 parts per million and hop, dried cones at 100 ppm. EPA's assessment of

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. Specific information on the studies received and the nature of the toxic effects caused by dithianon as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found either in the docket ID number HQ-EPA-2006-0623 at <http://www.regulations.gov> or at <http://www.epa.gov/oppr001/factsheets>.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/factsheets/riskassess.htm> or <http://www.epa.gov/oppfead1/trac/science>.

A summary of the toxicological endpoints for dithianon used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DITHIANON FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–49 years of age).	NOAEL = 20 mg/kg/day UF = 1,000 aAcute RfD = 0.02 mg/kg/day	Special FQPA SF = 1 aPAD = acute RfD/Special FQPA SF = 0.02 mg/kg/day	Developmental toxicity study in rats. LOAEL = 50 mg/kg/day based on post implantation loss due to early resorptions
Acute Dietary (General population including infants and children).	None	None	Not selected. No appropriate dose and end-point could be identified for these population groups.
Chronic Dietary (All populations) ..	NOAEL = 6 mg/kg/day UF = 1,000 a Chronic RfD = 0.006 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/ Special FQPA SF = 0.006 mg/kg/day	Combined chronic toxicity/ oncogenicity study in rats. LOAEL = 30 mg/kg/day based on decreased body weight gains and increased relative to body kidney weights (M and F), grossly observed kidney lesions in males (irregular surfaces, pale kidneys, cysts, and enlarged kidneys) and females (masses), and non-neoplastic lesions of the kidney in males (tubular nephrosis, renal cysts, and end-stage kidney lesions) and females (tubular nephrosis, proliferative tubules, and glomerulonephropathy).
Cancer (oral, dermal, inhalation)			Classification: Classification is "Suggestive Evidence of Carcinogenic Potential". The risk assessment for chronic effects is considered protective of any cancer effect.

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern, N/A = Not Applicable, ^a Additional 10x database uncertainty factor for lack of an acceptable developmental rabbit study.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have not been established for the residues of dithianon, in or on a variety of raw agricultural commodities because it is a new pesticide chemical. Risk assessments were conducted by EPA to assess dietary exposures from dithianon in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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 appropriate endpoint attributable to a single exposure for females 13–49 years of age was identified in the toxicological studies for dithianon, therefore, a quantitative acute dietary exposure assessment is necessary for this population. In conducting the acute dietary exposure 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 assessment. This acute analysis was based on tolerance-level residues, and an assumption of 100% crop treated.

No appropriate dose and endpoint could be identified attributable to a single exposure for the general population, including infants and children. Therefore, an acute dietary exposure assessment is not necessary for these populations.

ii. *Chronic exposure.* In conducting the chronic dietary exposure 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 chronic exposure assessment: This chronic analysis was based on anticipated (average) residues and an assumption of 100% crop treated. Exposure to dithianon would originate from food only, because the proposed tolerances would only be established on imported commodities. With no proposed U.S. registration, there is no expectation that dithianon residues would occur in surface or ground water sources of drinking water.

iii. *Cancer.* The Agency classified dithianon as having "Suggestive Evidence of Carcinogenicity", based on the presence of renal adenomas and carcinomas in the female rat at doses that were adequate to assess carcinogenicity. This classification is based on several weight-of-evidence

considerations. First treatment-related rare kidney tumors, primarily adenomas, were seen only at the highest dose tested (HDT) (600 ppm) in one sex (females) and in one species (rats). The HDT was considered adequate, but not excessive, to assess the carcinogenicity of dithianon; however, significant renal toxicity occurred at this dose. Second, there is no mutagenicity concern for dithianon. Finally, the Agency concluded that the registrant's hypothesized non-genotoxic mode of action involving nephrotoxicity and sustained regenerative proliferation is biologically plausible. The risk assessment for chronic effects is considered protective of any cancer effects.

2. *Dietary exposure from drinking water.* Since dithianon is proposed for use only on imported pome fruit and imported hops commodities, the sole anticipated exposure route for the U.S. population is via dietary (food) exposure. With no proposed U.S. registration, there is no expectation that dithianon residues would occur in surface or ground water sources of drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Dithianon is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of

toxicity, EPA has not made a common mechanism of toxicity finding as to dithianon and any other substances and dithianon 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 dithianon has a common mechanism of toxicity with other substances. For 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCFA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no indication of increased quantitative or qualitative susceptibility

of the offspring in the developmental and 2-generation reproduction studies. In the developmental toxicity study in rats, reductions in maternal body weights, body weight gains, and food consumption were seen at 50 mg/kg/day, but a higher dose (100 mg/kg/day) was required to produce a reduction in fetal body weights. The significant increase in post-implantation loss due to early resorptions occurred at 50 mg/kg/day, including dams that experienced total litter loss, is not evidence of increased qualitative susceptibility; instead, it is likely due to maternal toxicity. In the 2-generation reproduction study, decreased body weights, body weight gains, and food consumption were observed in the parents but no adverse effects were seen in the offspring up to the HDT.

3. *Conclusion.* The toxicology database shows no evidence of increased qualitative or quantitative susceptibility in the offspring. The dietary food exposure assessment utilizes tolerance level residues and 100% crop treated assumptions for acute risk, and average residues from crop field trials and 100% crop treated assumptions for chronic risk; by using these conservative assumptions, exposures/risks will not be underestimated. There are no existing or proposed residential uses for dithianon at this time. Nonetheless, because an acceptable rabbit developmental study is not available, the Agency retained the 10x FQPA safety factor, in the form of data base uncertainty factor of (UF_{DB}).

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* An acute endpoint was selected for only one population subgroup, females 13-49. Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that acute exposure to dithianon from food will utilize 66% of the aPAD for females 13 to 49 years of age.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE AND CHRONIC EXPOSURE TO DITHIANON

Population subgroup	Acute dietary (95th Percentile)*			Chronic dietary*		
	aPAD (mg/kg)	Exposure (mg/kg/day)	% aPAD	cPAD (mg/kg)	Exposure (mg/kg/day)	% cPAD
General U.S. Population	Not applicable.	Not applicable.	Not applicable.	0.006	.000738	12
All Infants <1 year	Not applicable.	Not applicable.	Not applicable.	0.006	0.003268	55
Children 1-2 years	Not applicable.	Not applicable.	Not applicable.	0.006	0.002773	46

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE AND CHRONIC EXPOSURE TO DITHIANON—Continued

Population subgroup	Acute dietary (95th Percentile)*			Chronic dietary*		
	aPAD (mg/kg)	Exposure (mg/kg/day)	% aPAD	cPAD (mg/kg)	Exposure (mg/kg/day)	% cPAD
Children 3-5 years	Not applicable.	Not applicable.	Not applicable.	0.006	0.001995	33
Children 6-12 years	Not applicable.	Not applicable.	Not applicable.	0.006	0.000903	15
Youths 13-19 years	Not applicable.	Not applicable.	Not applicable.	0.006	0.000313	5
Adults 20-49 years	Not applicable.	Not applicable.	Not applicable.	0.006	0.000583	10
Adults 50+ years	Not applicable.	Not applicable.	Not applicable.	0.006	0.000483	8
Females 13-49 years	0.02	.013119	66	0.006	0.000369	6

* Values for the population with the highest risk are bolded.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dithianon from food will utilize 12% of the cPAD for the U.S. population and 55% of the cPAD for all infants less than 1 year of age. There are no residential uses for dithianon that result in chronic residential exposure to dithianon.

3. *Short-term risk.* Dithianon is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the risk from food only, which does not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Dithianon is not registered for use on any sites that would result in residential exposure and is intended only for imported fruit, pome, group 11 and hops, dried cones. Therefore, the aggregate risk is the risk from food only, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* In accordance with EPA's Final Guidelines for Carcinogen Risk Assessment (March, 2005), the Agency classified dithianon into the category "Suggestive Evidence of Carcinogenicity", based on the presence of renal adenomas and carcinomas in the female rat at doses that were adequate to assess carcinogenicity. However, as noted in Unit.III.C.1.iii., the chronic risk assessment is protective of any possible cancer effect.

6. *Determination of safety.* 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 dithianon residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (HPLC/UV for pome fruit and HPLC/ECD for hops) is available to enforce the tolerance expression. 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

Codex MRLs have been established for residues of dithianon in or on pome fruit at 5 ppm and hops at 100 ppm; the proposed tolerances on imported commodities are harmonized with established MRLs. There are currently no established Canadian or Mexican MRLs for dithianon.

V. Conclusion

Therefore, a tolerance is established for residues of dithianon, 5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile, in or on imported fruit, pome, group 11 at 5 ppm and hop, dried cones at 100 ppm.

VI. Statutory and Executive Order Reviews

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

VII. 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: September 11, 2006.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.621 is added to read as follows:

§ 180.621 Dithianon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide dithianon, (5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile) in or on the following commodities:

Commodity	Parts per million
Fruit, pome, group 11 ¹	5
Hop, dried cones ¹	100

¹No U.S. registration as of September 5, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0613.; FRL-8089-2]

Etofenprox; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) in or on rice grain and rice straw. This action is associated with an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on rice. This regulation establishes a maximum permissible level for residues of etofenprox in these food commodities. The tolerances expire and are revoked on December 31, 2009.

DATES: This regulation is effective September 20, 2006. Objections and requests for hearings must be received on or before November 20, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0613. All documents in the docket are listed on the regulations.gov website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday