

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective January 1, 2007.

List of Subjects in 40 CFR Part 80

Environmental protection, Fuel additives, Gasoline, Imports, Labeling, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: September 14, 2006.

Stephen L. Johnson,
Administrator.

■ For the reasons set forth in the preamble, title 40, Chapter 1 of the Code of Federal Regulations is amended as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7545 and 7601(a).

■ 2. Section 80.285 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 80.285 Who may generate credits under the ABT program?

* * * * *

- (b) * * *
- (1) * * *

(ii) Refiners and importers of gasoline designated as GPA gasoline under § 80.219, using the least of 150.00 ppm, or the refinery's or importer's 1997–98 baseline calculated under § 80.295 plus 30.00 ppm, or the refinery's lowest annual average sulfur level for any year from 2000 through 2003 during which the refinery generated credits or allotments plus 30.00 ppm (for any

party generating credits under both paragraphs (b)(1)(i) of this section and this paragraph (b)(1)(ii), such credits must be calculated separately); or

* * * * *

■ 3. Section 80.310 is amended by revising paragraphs (a) and (b) to read as follows:

§ 80.310 How are credits generated beginning in 2004?

(a) A refiner for any refinery, or an importer, may generate credits in 2004 and thereafter if the annual average sulfur level for gasoline produced or imported for the averaging period is less than 30.00 ppm; or, for refiners that are subject to the small refiner standards in § 80.240, the small refiner annual average sulfur standard applicable to that refinery; or, for refiners and importers subject to the GPA standards in § 80.216, the least of 150.00 ppm, or the refinery's or importer's 1997–1998 sulfur level calculated under § 80.295 plus 30.00 ppm, or the refinery's lowest annual average sulfur level for any year from 2000 through 2003 during which the refinery generated credits or allotments plus 30.00 ppm.

(b) Credits are calculated as follows:

$$CR_a = V_a \times (S_{Credit} - S_a)$$

Where:

CR_a = Credits generated for the averaging period.

V_a = Total annual volume of gasoline produced at a refinery or imported during the averaging period.

S_{Credit} = 30.00 ppm; or the sulfur standard for a small refinery established under § 80.240; or, for gasoline designated as GPA gasoline under § 80.219, the least of 150.00 ppm, or the refinery's or importer's 1997–1998 sulfur level calculated under § 80.295 plus 30.00 ppm, or the refinery's lowest annual average sulfur level for any year from 2000 through 2003 during which the refinery generated credits or allotments plus 30.00 ppm.

S_a = Actual annual average sulfur level, calculated in accordance with the provisions of § 80.205, for gasoline produced at a refinery or imported during the averaging period, exclusive of any credits.

* * * * *

■ 4. Section 80.415 is amended by revising paragraph (a)(2)(iii) to read as follows:

§ 80.415 What are the attest engagement requirements for gasoline sulfur compliance applicable to refiners and importers?

* * * * *

- (a) * * *
- (2) * * *

(iii) If the annual average sulfur level for any year in which credits were

generated for 2000 through 2003 was less than the baseline level under paragraph (a)(1) of this section, for small refiners report as a finding the lowest annual sulfur level as the new baseline value for purposes of establishing the small refiner standards under § 80.240, and for GPA gasoline report as a finding the lowest annual sulfur level plus 30.00 ppm as the new sulfur level for purposes of credit generation under § 80.310, if lower than 150.00 ppm.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0324; FRL–8093–7]

Metrafenone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on imported grape at 0.6 parts per million (ppm), with no U.S. registration. 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–2006–0324. 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Janet Whitehurst, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6129; e-mail address: janet.whitehurst@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0324 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-2006-0324, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of May 10, 2006 (71 FR 27242-27243) (FRL-8058-2), 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 4E6884) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.624 be amended by establishing a tolerance for residues of the fungicide metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on imported table and wine grapes, at 0.5 ppm. That notice included a summary of the petition prepared by BASF Corporation, the registrant. The registrant is seeking a tolerance on imported grapes and its processed commodities. Following review of the residue data, EPA has increased the tolerance level for grapes from 0.5 ppm to 0.6 ppm and concluded that tolerances are not necessary for processed grape commodities. EPA’s statistical analysis of the residue data indicates that 0.6 ppm better represents a value that should not be exceeded in grapes and processed grape commodities by any application of the pesticide in conformity with its uses. Tolerances are not necessary for processed grape commodities because residues on those commodities are unlikely to exceed the 0.6 ppm level in the grape tolerance. Under the FFDCA, tolerances for raw agricultural commodities also apply to processed foods made from the raw commodities (21 U.S.C. 346a(a)(2)). Comments were received on the notice of filing. EPA’s response to these comments are discussed in Unit IV.C.

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 FFDCA and a complete description of the risk assessment process, see:

- <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.
- <http://www.epa.gov/oppfead1/trac/science>.
- <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.
- <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>.

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 metrafenone on grape at 0.6 ppm with no U.S. registration. EPA's assessment of exposures and risks associated with establishing the import 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 toxicology database for metrafenone is complete and adequate for selection of doses and endpoints to be used in this risk assessment. The toxic effects caused by metrafenone are discussed in a document entitled, *Metrafenone: Human Health Risk Assessment for Proposed Use on Grapes* that can be found at <http://www.regulations.gov> in the docket ID number EPA-HQ-OPP-2006-0324.

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>.
- <http://www.epa.gov/oppfead1/trac/science>.

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

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

Exposure scenario	Dose used in risk assessment, UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL= 25 milligram/kilogram/day (mg/kg/day) UF=100 Chronic RfD=0.25mg/kg/day	cPAD= cRfD/Special FQPA SF Special FQPA SF = 1 cPAD= 0.25	Combined chronic/carcinogenicity—rat LOAEL 260 (mg/kg/day): Based on hepatotoxicity and nephrotoxicity in both sexes.
Cancer (Oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenicity." The chronic RfD is protective of cancer effects.		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been proposed (40 CFR 180.624) for the residues of metrafenone, in or on imported table and wine Grapes. There are no registrations for use of metrafenone in the United States. There are no major livestock feed items associated with the use on imported grapes. Therefore, residues in livestock commodities are not relevant to the establishment of import tolerances for grapes. Risk assessments were conducted by EPA to assess dietary exposures from metrafenone 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 1-day or single exposure.

No acute reference dose was established nor was a dietary endpoint identified in either the general population or for females aged 13–49 years. There were no appropriate studies that demonstrated evidence of toxicity attributable to a single dose of metrafenone for these populations. As a result, a quantitative acute dietary exposure assessment is unnecessary.

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 U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The dietary assessment included just grapes, the only source of residues for metrafenone. It was assumed that 100% of all grape commodities contained tolerance level residues.

iii. *Cancer.* Although metrafenone is considered to be a possible human carcinogen, the risk assessment based on chronic effects is considered protective of cancer effects; therefore, a

cancer dietary analysis was not performed. EPA classified metrafenone as "Suggestive Evidence of Carcinogenicity," and concluded that human risk to liver tumorigenesis would not be expected at exposure levels that do not cause tumors in mice. The NOAEL and LOAEL selected for the cRfD are based on hepatotoxicity and nephrotoxicity observed at doses lower than the liver tumor response dose. Thus, the cRfD is protective of the cancer effects. This conclusion was based on the following weight-of-evidence considerations:

a. There was a treatment-related increase in hepatocellular adenomas and adenomas plus carcinomas in male mice and only at the highest dose tested (HDT) (limit dose) of 1,109 mg/kg/day. Although there was an increase in the incidence of hepatocellular adenomas in female rats, this increase occurred only at the HDT, 1,493 mg/kg/day, which was considered by the EPA to be above the maximum tolerated dose (MTD) and, therefore, was not relevant.

b. There were no treatment-related tumors seen in male rats or female mice.

c. Metrafenone did not appear to be genotoxic.

d. The registrant submitted three "mode of action" studies in rats. The EPA considered that, because the increased incidence in tumors in rats occurred at a dose above the MTD, these studies could not be used to explain the mode of action. The registrant did not submit any "mode of action" studies in mice. Therefore, as EPA considered an increase in hepatocellular adenomas and adenomas plus carcinomas to be relevant only in mice, it was determined that no "mode of action" studies were applicable to these tumors. EPA indicated that the results of the mode of action studies in rats could not be "assumed" to be relevant in the mouse.

iv. *Anticipated residue and percent crop treated (PCT) information.* Anticipated residues and PCT data were not used for the conservative dietary exposure analysis.

2. *Dietary exposure from drinking water.* As there are no U.S. registrations or proposed registrations, residues are not expected in 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).

Metrafenone 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 FFDCA 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 metrafenone and any other substances and metrafenone 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 metrafenone 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 FFDCA 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 database 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 UFs (safety) 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 UFs and/or special FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity.* The toxicology database for metrafenone is complete and adequate to characterize potential pre- and/or postnatal risk for infants and children. Acceptable/guideline studies for developmental toxicity in rats and rabbits as well as a 2-generation reproduction study in rats

were available for consideration during endpoint selection.

3. *Conclusion.* After evaluating the toxicological and exposure data, EPA recommends that the FQPA SF be reduced to 1X because:

i. The toxicology database is complete.

ii. There was no evidence of increased qualitative or quantitative susceptibility observed in the rat or rabbit developmental as well as the rat reproduction studies; there are no residual uncertainties with regard to pre- and postnatal toxicity.

iii. The dietary food exposure assessment is based on EPA-recommended tolerance-level residues and assumes 100% crop treated for all commodities, which results in very high-end estimates of dietary exposure.

iv. The proposed use is for import tolerances; therefore, residential and occupational exposures are not anticipated.

E. Aggregate Risks and Determination of Safety

In accordance with the FQPA, EPA must consider and aggregate pesticide exposures and risks from three major sources: Food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure.

The registrant is seeking import tolerances on grapes and its processed commodities and the risk assessment includes only dietary exposure to metrafenone. There is no expectation that exposure to metrafenone would occur via water consumption or residential use. Therefore, an aggregate exposure risk assessment is equivalent to the dietary risk assessment.

1. *Acute risk.* Because there was no evidence of toxicity for metrafenone attributable to a single dose, metrafenone is not expected to pose an acute risk.

2. *Chronic risk.* As there are no U.S. registrations or proposed registrations, the chronic aggregate risk is equivalent to the chronic dietary risk. Based on the exposure assumptions discussed in this unit, the chronic exposure for the general U.S. population is 0.1% of the cPAD. The most highly exposed population subgroup is children 1–2 years, which utilizes 0.8% of the cPAD. The dietary risk estimates are all below EPA's level of concern.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). As there are no U.S. registrations or proposed registrations for metrafenone, there will be no exposures from residential uses or residues in drinking water. Therefore, the aggregate risk is the risk from food (grape commodities) only. The dietary risk estimates are all below EPA's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). As there are no U.S. registrations or proposed registrations for metrafenone, there will be no exposures from residential uses or residues in drinking water. Therefore, the aggregate risk is the risk from food (grape commodities) only. The dietary risk estimates are all below EPA's level of concern.

5. *Aggregate cancer risk for U.S. population.* EPA considers the cRfD to be protective of the cancer effects and, as indicated in this unit, exposure is well below this level.

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 metrafenone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has submitted gas chromatography methods with electron capture and mass selective detection for determining residues of metrafenone in grapes and wine. These methods are considered adequate for tolerance enforcement purposes. In addition, there is good recovery of metrafenone from grapes using the Food and Drug Administration (FDA) multi-residue method protocols. The metrafenone methods 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

There are no specific CODEX maximum residue limits (MRLs) for metrafenone. Although the European Food Safety Authority has proposed a European Union MRL of 0.5 ppm for grapes, the MRL has yet to be harmonized between member states.

The registrant is seeking import tolerance on grapes and its processed commodities. Following review of the residue and metabolism data, EPA has made a minor change to the proposed tolerance. For grapes EPA expanded the tolerance level for grapes from 0.5 ppm to 0.6 ppm.

C. Response to Comments

One comment, dated May 10, 2006, was received from B. Sachau. Ms. Sachau's comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to metrafenone, including all anticipated dietary exposures and other exposures for which there is reliable information. This comment as well as her comments regarding animal testing have been responded to by the Agency on several occasions. For examples, see the **Federal Register** issues of January 7, 2005 (70 FR 1349) (FRL-7691-4) and October 29, 2004 (69 FR 63083) (FRL-7681-9).

V. Conclusion

Therefore, the tolerance is established for residues of metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on grape at 0.6 ppm, with no U.S. registration.

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 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