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: May 14, 2007.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1206 is amended by designating the existing text as paragraph (a) and by adding paragraph (b) to read as follows:

§ 180.1206 Aspergillus flavus AF36 on pistachio; exemption from the requirement of a tolerance.

(a) * * *

(b) *Apergillus flavus* AF36 is temporarily exempt from the requirement of a tolerance on pistachio when used in accordance with the Experimental Use Permit 71693-EUP-1. This temporary exemption from tolerance will expire on May 14, 2010.

[FR Doc. E7–9729 Filed 5–22–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0820; FRL–8131–4]

Coumaphos; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of coumaphos in or on honey and honeycomb. Interregional Research Project #4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 23, 2007. Objections and requests for hearings must be received on or before July 23, 2007, 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–2006–0820. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. 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: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address:*madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- 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 to provide 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2006–0820 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 as required by 40 CFR part 178 on or before July 23, 2007.

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 this copy, identified by docket ID number EPA–HQ–OPP–2006–0820, by one of the followingmethods:

- *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. Petition for Tolerance

In the **Federal Register** of October 18, 2006 (71 FR 61465) (FRL–8097–9), 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 2E6504) by Interregional Research Project #4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.189 be amended by establishing a tolerance for residues of the insecticide coumaphos (O,O -diethyl O -3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate) and its oxygen analog (O,O -diethyl O -3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate) in or on honey at 0.10 parts per million (ppm) and honeycomb at 100 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has determined tolerance levels for honey and honeycomb should be modified. The reason for these changes is explained in Unit V. EPA is also deleting the established tolerances in §180.189(b) for honey and honeycomb that are no longer needed. The tolerance deletions under §180.189(b) are time-limited tolerances established under section 18 emergency exemptions that are superceded by the establishment of general tolerances for coumaphos under §180.189(a).

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of the FFDCA, and the factors specified in 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 and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of coumaphos (O,O -diethyl O -3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate) and its oxygen analog (O,O -diethyl O -3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate) on honey at 0.15 ppm and honeycomb at 45 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 adverse effects caused by coumaphos as well as the NOAEL and the LOAEL from the toxicity studies can be found in the Reregistration Eligibility Decision (RED) for coumaphos (*http://www.epa.gov/oppsrrd1/REDs/0018.pdf*), the Reregistration Eligibility Decision Addendum and FQPA Tolerance Reassessment Progress Report (TRED) for coumaphos (*http://www.epa.gov/oppsrrd1/REDs/0018tred.pdf*) and at *www.regulations.gov* in document Coumaphos: Human Health Risk Assessment for Proposed Use on Honey and Honeycomb page 11 in Docket ID EPA–HQ–OPP–2006–0820.

The mammalian toxicology database for coumaphos is complete. Acute toxicity studies in rats and rabbits; an acute delayed neurotoxicity study in hens; subchronic oral and dermal studies in rats; chronic/carcinogenicity studies in rats, mice, and dogs; developmental toxicity studies in rats and rabbits; a 2-generation study in rats; mutagenicity studies; and a metabolism study were discussed and considered in the Reregistration Eligibility Decision (RED) for coumaphos (*http://www.epa.gov/oppsrrd1/REDs/0018.pdf*). Acute and subchronic neurotoxicity studies in rats were received subsequent to the RED and were considered in the RED Addendum and FQPA Tolerance Reassessment Progress Report (TRED) for coumaphos (*http://www.epa.gov/oppsrrd1/REDs/0018tred.pdf*). Subsequent to the TRED, a developmental neurotoxicity study and a comparative cholinesterase study in rats were received; these studies are discussed in detail at www.regulations.gov in document Coumaphos: Human Health Risk Assessment for Proposed Use on Honey and Honeycomb at page 11 in Docket ID EPA–HQ–OPP–2006–0820.

The acute toxicity of coumaphos is high via the oral route of exposure (Category I), moderate via the inhalation route (Category II), and slight via the dermal route (Category III). Coumaphos is not a dermal sensitizer or a dermal irritant.

Coumaphos, an organophosphate insecticide, primarily affects the nervous system through cholinesterase (ChE) inhibition. Females are consistently more sensitive to the cholinergic effects than males. In the acute oral toxicity studies, female rats are approximately 17 times more sensitive to the toxic and lethal effects of coumaphos compared to male rats. In a single dose oral study, female rats had ChE inhibition and cholinergic symptoms at much lower doses than male rats. In a short-term (5 days) dermal toxicity study, brain ChE inhibition was the most sensitive

indication of the toxic effects of coumaphos dermal treatment. In subchronic and chronic studies in rats, the magnitude of ChE inhibition in red blood cell and plasma and brain was also more pronounced in females, compared to males. Coumaphos does not cause delayed neuropathy. In chronic studies, systemic effects other than cholinergic toxicity include decreases in body weight gain.

There was no evidence of malformations or decreases in the number of pups and/or litter or surviving offspring in any of the developmental toxicity or reproduction studies. In developmental toxicity studies in rats and rabbits, no developmental toxicity was observed, while clinical signs of ChE toxicity were seen in the maternal animals. In a 2-generation reproduction study, ChE inhibition was noted in both parents and offspring, with parents more susceptible. Reproductive toxicity was not observed in this study.

The developmental neurotoxicity study showed no increased susceptibility of the young. The maternal ChE activity was inhibited at both the mid and high does. Consistent with the other mammalian toxicity studies, female pups were more sensitive to cholinergic effects than males; at the high dose, female plasma, erythrocyte, and brain ChE activities were inhibited 27%, 33%, and 8%, respectively, but only plasma ChE activity was significantly inhibited (30%) at this dose in males. In the comparative ChE study increased quantitative susceptibility of the offspring was observed in that ChE inhibition was seen at a lower dose in neonatal rats, compared to young adult rats. The relative sensitivities to ChE inhibition at peak inhibition by coumaphos were measured in neonatal and young adult rats. This comparative ChE study does demonstrate increased quantitative susceptibility of the offspring. However, the degree of concern for this comparative ChE study is low because the effects are well characterized and there are clear no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) for both neonatal and adult animals. Furthermore, there are no residual uncertainties for prenatal and/or postnatal toxicity for the comparative ChE study because the endpoint of concern is the one used for the acute dietary exposure risk assessment and a more protective endpoint (based on long term-exposure) is used for chronic dietary exposure risk assessment.

Coumaphos is not carcinogenic and is classified as a Group E chemical, indicating that it is ''Not Likely'' to be carcinogenic in humans via relevant routes of exposure. This classification is based on adequate studies in two animal species. No evidence of mutagenicity was seen in any study.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which the LOAEL of concern are identified is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population (cPAD) adjusted dose. The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-term, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threhold risk, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA used in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for coumpahos used for human risk assessment can be found at www.regulations.gov in document Coumaphos: Human Health Risk Assessment for Proposed Use on Honey and Honeycomb page 15 in Docket ID EPA–HQ–OPP–2006–0820.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to coumaphos, EPA considered exposure under the petitioned-for tolerances as well as all existing coumaphos tolerances in (40 CFR 180.189). EPA assessed dietary exposures from coumaphos and coumaphos-oxon 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

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues incorporating 2002 (USDA) Pesticide Data Program (PDP) monitoring data for beef and 2004 PDP monitoring data for milk. Field trial data were used for honey to support the proposed use pattern. The dietary exposure assessment assumes 100% crop treated for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues incorporating 2002 USDA PDP monitoring data for beef and 2004 PDP monitoring data for milk. Field trial data were used for honey to support the proposed use pattern. The dietary exposure assessment assumes 100% crop treated for all commodities.

iii. *Cancer*. Coumaphos is not carcinogenic and is classified as a Group E chemical, indicating that it is ''Not Likely'' to be carcinogenic in humans via relevant routes of exposure. Therefore, the Agency concluded that coumaphos is not expected to pose a carcinogenic risk and quantification of cancer risk is not required.

iv. *Anticipated residue information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) and authorized under section 408(f)(1) of the FFDCA. Data will be required to be

submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for coumaphos in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of coumaphos. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

The generic expected environmental concentration (GENEEC) and screening concentration in groundwater (SCI-GROW) screening models were used to estimate surface water and ground water concentrations of coumaphos and its oxygen analog, coumaphoxon. This degradate is considered in the drinking water assessment, as it was in the assessment for consumption of food (honey and livestock commodities). Based on the GENEEC and SCI-GROW models, the estimated environmental concentrations (EECs) of coumaphos and its oxygen analog, coumaphoxon for acute exposures are estimated to be 1.86 parts per billion (ppb) for surface water and 0.17 ppb for ground water. The EECs for chronic exposures are estimated to be 0.41 ppb for surface water and 0.17 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 1.86 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.41 ppb was used to assess the contribution to 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).

Coumaphos 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 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.''

FQPA (1996) stipulates that when determining the safety of a pesticide chemical, the EPA shall consider, among other things, available information concerning the cumulative effects on human health that may result from dietary, residential, or other non-occupational exposure to the pesticide chemical and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. A person exposed to a pesticide at a level that is considered safe may, in fact, experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

The organophosphate pesticides (OPs) were established as the first common mechanism group by EPA in 1999, based on their shared ability to bind to and phosphorylate the enzyme acetylcholinesterase in both the central (brain) and peripheral nervous systems. Coumaphos is an OP pesticide. In December 2001, the Agency issued the ''Preliminary OP Cumulative Risk Assessment'', available at *http://www.epa.gov/pesticides/cumulative/pra_op_methods.htm*. In June 2002, the Agency released its Revised OP CRA, available at *http://www.epa.gov/pesticides/cumulative/rra-op/*, which included the cumulative risk due to the OPs from exposures in food, drinking water, and residential uses. In August 2006, the Agency issued an update to the 2002 Revised OP CRA document, which emphasized changes, modifications, and amendments. With the 2006 update, available at *http://www.epa.gov/pesticides/cumulative/2006-op/index.htm*, the Agency has developed a highly refined and complex cumulative risk assessment for the OPs that represents the state of the science regarding existing hazard and exposure data and the models and approaches used. Based upon the results from the 2006 update, the Agency concluded that the results of the OP cumulative risk assessment support a reasonable certainty of no harm finding.

In both the 2002 revised OP CRA, as well as the 2006 update, the cumulative dietary risk associated with the use of OP pesticides on food crops was assessed using residue monitoring data collected by the USDA PDP and dietary consumption data collected by USDA's Survey of Food Intakes by Individuals (CSFII). Both assessments relied primarily on the PDP for residue data; the 2006 update added PDP data collected in 2002–2004 to the 1994–2001 data used in the 2002 Revised Assessment. The PDP has been collecting pesticide residue data since 1991, primarily for purposes of estimating dietary exposure. The program focuses on high-consumption foods for children and reflects foods typically available throughout the year. A complete description of the PDP and all data through 2004 are available online (*http://www.ams.usda.gov/science/pdp*). No PDP data on honey currently exist that could have been used in a cumulative assessment. OP residues in honey were not included in the PDP data base, in part because honey is a low-consumption food. A quantitative estimate of honey consumption over a single day was obtained for the general U.S. population and subpopulations using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's CSFII from 1994-1996 and 1998. Consumption estimates at the 99.9th percentile of exposure range from 21 grams of honey/day in all infants (<1 year) to 96 grams/day in adults 50 + years, the population subgroup who reported the greatest amount of honey consumed. Estimates of honey consumption for all other subpopulations, including children 1-2, 3-5, and 6-12 years; youth 13-19 years; females 13-49 years; and adults 20-49 years are within this range.

Although PDP data on coumaphos data in honey is not available, monitoring for coumaphos in honey is conducted under the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition (CFSAN) Surveillance Monitoring Program. This monitoring program is designed primarily for enforcement of EPA pesticide tolerances on imported foods and domestic foods shipped in interstate commerce. In this monitoring program, domestic samples are generally collected close to the point of production in the distribution system. Import samples are collected at the point of entry into U.S commerce. The emphasis in sample collection is on the agricultural commodity, which is analyzed as the unwashed, whole (unpeeled), raw commodity. Processed foods are also included in the program.

A description of the program and residue data for recent years can be found online (*http://vm.cfsan.fda.gov/~lrd/pestadd.html*). Because the emphasis of this program is not on dietary exposure, it was used in the 2006 cumulative assessment mostly as a semi-quantitative check on the potential for residues and as support for data from other sources. Data are available from 1996–2003. Although the Agency has granted emergency exemptions, starting in 1999, such that the coumaphos strips assessed in this document have been and continue to be used on beehives in 40–46 states (*http://www.epa.gov/opprd001/section18*), the FDA has detected coumaphos in honey only once, in 2003, at levels lower than the level of quantification. Thus, FDA data indicates that there is a low expectation of meaningful coumaphos residues in honey.

EPA does not believe that inclusion of anticipated coumaphos residues in honey in the OP CRA will significantly modify the calculated risk. This conclusion is based on three factors. First, honey is a low consumption food, and, thus, even if honey contained quantifiable levels of OPs, it would be unlikely to significantly alter the OP CRA. Second, available monitoring data indicates that, despite widespread use of coumaphos, residues of coumaphos in honey as consumed are exceedingly low, if present at all. Finally, a prior risk assessment for coumaphos indicated that aggregate risk from coumaphos was essentially unchanged when honey containing levels of coumaphos residues found in field trials was added to the coumaphos risk assessment, August 16, 2000 (65 FR 49927) (FRL–6738–3). In the current assessment, no discernible difference in exposure was observed when coumaphos residues in honey and beeswax were or were not included in an aggregate assessment (personal correspondence, S. Piper, January 1, 2007). If coumaphos exposure from honey is insignificant in comparison to exposure to coumaphos from other uses of the chemical, it necessarily is insignificant in comparison to exposure to the more than 30 other OPs. For these reasons, EPA concludes that the establishment of a coumaphos honey tolerance will not raise a concern regarding cumulative OP exposure.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased qualitative or quantitative susceptibility of the offspring in the developmental, reproduction, or developmental neurotoxicity studies. Increased quantitative susceptibility of the offspring was observed in the comparative ChE study in that ChE inhibition was seen at a lower dose in neonatal rats, compared to young adult rats. The degree of concern for this comparative ChE study is low because the effects are well characterized and there are clear NOAELs and LOAELs for both neonatal and adult animals. Furthermore, there are no residual uncertainties for pre- and/or postnatal toxicity for the comparative ChE study because the endpoint of concern is the one used for the acute dietary exposure risk assessment and a more protective endpoint (based on long-term exposure) is used for chronic dietary exposure risk assessment.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for coumaphos is complete.

ii. As discussed in Unit III.D.2., there are no residual uncertainties regarding prenatal or postnatal toxicity or increased sensitivity of the young.

iii. There are no residual uncertainties identified in the exposure data bases. The dietary food exposure assessments were performed based on 100% crop treated and using reliable data (USDA PDP data for meat and milk and field trial data for honey) and will not underestimate the exposure and risk. Conservative ground water and surface water modeling estimates were used. These assessments will not underestimate the exposure and risks posed by coumaphos.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to coumaphos will occupy 15% of the aPAD for the U.S. population and 38% of the aPAD for all infants (< 1 year), the most highly exposed population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to coumaphos from food and water will utilize 6% of cPAD for the U.S. population and 13% of the cPAD for all infants (< 1 year), the most highly exposed population subgroup. There are no residential uses for coumaphos that result in chronic residential exposure to coumaphos.

3. *Short-term and Intermediate-term risk*. Short-term and intermediate aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Coumaphos is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Aggregate cancer risk for U.S. population*. Coumaphos is not carcinogenic and is classified as a Group E chemical, indicating that it is ''Not Likely'' to be carcinogenic in humans via relevant routes of exposure. This classification is based on adequate studies in two animal species. Coumaphos is not expected to pose a cancer risk.

5. *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, or to infants and children from aggregate exposure to coumaphos residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography/mass spectroscopy/ mass spectroscopy (LC/MS/MS) 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

There are no CODEX, Canadian, or Mexican maximum residue limits (MRLs) for residues of coumaphos in honey or honeycomb. Therefore, harmonization with international tolerances is not an issue for this action.

C. Response to Comments

Several comments were received from a private citizen objecting to establishment of tolerances. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** June 30, 2005 (70 FR 37686) (FRL–7718–3), January 7, 2005 (70 FR 1354) (FRL–7691–4) and, October 29, 2004 (69 FR 63096) (FRL–7681–9) for the Agency's response to these objections.

V. Conclusion

Based upon review of the residue field trial data supporting the petition, EPA has determined tolerance levels for honey and honeycomb should be modified and tolerances levels should be 0.15 ppm for honey and 45 ppm for honeycomb.

Therefore, tolerance are established for residues of coumaphos (O,O -diethyl O -3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate and its oxygen analog (O,O -diethyl O -3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate) on honey at 0.15 ppm and honeycomb at 45 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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), Pub. L. 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: May 15, 2007.

Daniel J. Rosenblatt,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.189 is amended by alphabetically adding commodities to the table in paragraph (a), and in paragraph (b), the text and table are removed and the paragraph is reserved to read as follows:

§ 180.189 Coumaphos; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Honey	0.15
Honeycomb	45.0
* * * * *	

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

* * * * *

[FR Doc. E7–9813 Filed 5–22–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0332; FRL–8128–6]

Famoxadone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of famoxadone in or on grape, hop, and caneberry, Subgroup 13A. Interregional Research Project (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 23, 2007. Objections and requests for hearings must be received on or before July 23, 2007, 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–2006–0332. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. 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: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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 those engaged in the following activities:

- 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 to provide 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e–CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2006–0332 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 as required by 40 CFR part 178 on or before July 23, 2007.

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 this copy, identified by docket ID number EPA–HQ–OPP–2006–0332, 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. Petition for Tolerance

In the **Federal Register** of May 10, 2006 (71 FR 27247) (FRL–8067–5) and November 22, 2006 (71 FR 67572) (FRL–8101–9), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 5E7001 (grape and hop), and PP 6E7099 (caneberry) by the IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.587