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 FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: August 4, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

§ 180.434 [Amended]

2. In § 180.434, amend the table in paragraph (b), by revising the revocation/expiration date for ''Cranberries,'' ''Sorghum, aspirated grain fractions,'' ''Sorghum, grain, grain,'' and ''Sorghum, grain, stover'' from ''7/31/00'' to read ''12/31/01'' and by revising the revocation/expiration date for ''Blueberries,'' ''Dry bean forage,'' ''Dry bean hay,'' ''Dry beans,'' and ''Raspberries'' from ''12/31/00'' to read ''12/31/01''.

[FR Doc. 00–20733 Filed 8–15–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301039; FRL–6738–3]

RIN 2070–AB78

Coumaphos; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate) and its oxygen analog, coumaphoxon (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate in or on honey and beeswax. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide in beehives. This regulation establishes maximum permissible levels for residues of coumaphos in these food commodities. These tolerances will expire and are revoked on December 31, 2002.

DATES: This regulation is effective August 16, 2000. Objections and requests for hearings, identified by docket control number OPP–301039, must be received by EPA on or before October 16, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301039 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463; and 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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301039. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI).

This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined 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, coumaphoxon (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate, in or on honey at 0.1 part per million (ppm) and beeswax at 100 ppm. These tolerances will expire and are revoked on December 31, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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

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

III. Emergency Exemption for Coumaphos on Honey and Beeswax and FFDCA Tolerances

The varroa mite (*Varroa jacobsoni* Oudemans) is an ectoparasite of honey bees. It was first detected in the continental United States in Maryland in 1979, and found in Florida and Wisconsin by 1987. Currently it is the most important pest of honey bee colonies. The mites feed on the hemolymph of the developing bee larva, pupa, and adult bees. Dead or dying newly emerged bees have malformed wings, legs, abdomens, and thoraces. Recent anecdotal evidence suggests that bee viruses and varroa mites are closely linked to the demise of honey bee colonies. The mites have been shown to activate some of these, usually benign, viruses; causing virus outbreaks that ultimately lead to colony mortality.

Fluvalinate is currently registered for the control of varroa mites however, populations of varroa mites have developed resistance to fluvalinate. Varroa mite resistance to fluvalinate has been well documented by the United States Department of Agriculture (USDA), Agricultural Research Service (ARS). According to USDA, ARS many hives treated with fluvalinate have resulted in wholesale colony losses. Due to the destructive nature of this pest coupled with the importance of honey bees (for honey production and pollination of numerous agricultural crops) to the U.S. economy, it is imperative that alternative means of controlling the varroa mite be developed. Currently, coumaphos is the only pesticide that has been identified as an effective alternative to fluvalinate. Extensive efficacy trials, performed in laboratories in the U.S.A. and abroad, have revealed that coumaphos will significantly reduce populations of varroa mites without causing any appreciable mortality to adult honey bees or their brood.

The small hive beetle (*Aethina tumida* Murray) was discovered for the first time in the continental U.S. (in Florida) in May 1998. The beetles infest European honey bee colonies and feed on stored pollen and honey. The adult beetles have a thick integument that protects them from bee stings. Hive combs are destroyed and developing bee broods are killed by the burrowing of the beetle larvae throughout the hive. Also, the excrement of these hive beetles fouls the honey, reducing its quality. Currently there are no pesticides registered for the control of small hive beetles.

The Agency has authorized the use of coumaphos under section 18 of FIFRA for the use of coumaphos impregnated in plastic strips to be hung in beehives to control varroa mites and small hive beetles to 45 States. To date based on studies conducted by USDA, ARS, no chemical other than coumaphos is available that provides reliable, effective control of both varroa mites and/or small hive beetles. To date, resistant strains of honey bees, biological control methods, and the use of other natural products are not completely functional management practices. The EPA did register formic acid during 1999. However it is only registered for suppression of varroa mites and is not labeled for control of small hive beetles. USDA, ARS has stressed that formic acid alone is not a viable replacement for fluvalinate.

The Agency has concluded that not only would beekeepers be adversely impacted if these emergency exemptions were not granted but that the impact on much of agriculture in the United States could be dire. That is, if coumaphos is not made available to control varroa mites and small hive beetles beekeepers and honey producers in at least 45 states will suffer significant economic losses. Additionally, much of agriculture in America will be adversely impacted. Few feral bee colonies remain in the United States due to disease and insect pressure (including that from varroa mites), increasing the American farmers dependency on managed bees for pollination. Over 150 crops have been identified that require bees for pollination. Based on figures published by the National Agricultural Statistics Service of USDA the estimated value of increased yield and quality achieved through pollination by honey bees is 14.6 billion dollars per year.

In 1999, based on limited residue data available in which honey and wax samples were collected from brood chambers, the Agency concluded that there would be no reasonable expectation of residues of coumaphos in commercial honey and processed beeswax used for food (taken from the honey supers) provided that the coumaphos strips were used in brood chambers when honey supers were not present (in accordance with the section 18 authorization letter). Therefore, the section 18 use was classified as a non-food use and no tolerances were established in either honey or beeswax. However, based on additional information submitted to the Agency in 2000 the non-food use classification is no longer supportable and establishing tolerances for honey and beeswax is necessary.

EPA has authorized under FIFRA section 18 the use of coumaphos in beehives for control of varroa mites and small hive beetles in Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Minnesota, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, and Wyoming. After having reviewed these submissions, EPA concurs that emergency conditions exist.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of coumaphos in or on honey and beeswax. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on honey and beeswax after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether coumaphos meets EPA's registration requirements for use on honey and beeswax or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of coumaphos by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any other State to use this pesticide in beehives under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for coumaphos, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of coumaphos and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of coumaphos (O,O-diethyl O-3- chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate) and its oxygen analog, coumaphoxon (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate in or on honey at 0.1 ppm and beeswax at 100 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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 endpoint. 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences. For coumaphos an extra UF of 3 (for a total UF of 300) was applied for acute dietary, short term inhalation, and intermediate term inhalation assessments to account for the lack of a NOAEL in the toxicology studies identified for use in these risk assessments.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD=NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE)=NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is

typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR COUMAPHOS FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute Dietary females 13–50 years of age	LOAEL = 2.0 mg/kg/day; UF = 300; Acute RfD = 0.007 mg/kg/day	FQPA SF = 1; aPAD = acute RfD; FQPA SF = 0.007 mg/kg/day	Acute Oral Neurotoxicity study LOAEL = 2.0 mg/kg/day based on plasma and RBC cholinesterase inhibition in both males and females. A NOAEL for cholinesterase inhibition was not established.
Acute Dietary general population including infants and children	LOAEL = 2.0 mg/kg/day; UF = 300; Acute RfD = 0.007 mg/kg/day	FQPA SF = 1; aPAD = acute RfD; FQPA SF = 0.007 mg/kg/day	Acute Oral Neurotoxicity study LOAEL = 2.0 mg/kg/day based on plasma and RBC cholinesterase inhibition in both males and females. A NOAEL for cholinesterase inhibition was not established.
Chronic Dietary all populations	NOAEL = 0.025 mg/kg/day; UF = 100; Chronic RfD = 0.0003 mg/kg/day	FQPA SF = 1; cPAD = chronic RfD; FQPA SF = 0.0003 mg/kg/day	1–Year Feeding study in dog LOAEL = 0.77 mg/kg/day based on significant and biologically relevant depression of RBC ChE and plasma ChE activity levels.
Short-Term Dermal (1 to 7 days) (Residential)	dermal study NOAEL = 5.0 mg/kg/day (dermal absorption rate = 100%)	LOC for MOE = 100 (Residential)	5-Day Dermal toxicity study in rats LOAEL = 10 mg/kg/day based on brain cholinesterase inhibition in female rats.
Intermediate-Term Dermal (1 week to several months) (Residential)	dermal study NOAEL = 0.5 mg/kg/day (dermal absorption rate = 100%)	LOC for MOE = 100 (Residential)	21-Day Dermal Study in the rat LOAEL = 1.1 mg/kg/day based on RBC cholinesterase inhibition in female rats.
Long-Term Dermal (several months to lifetime) (Residential)	None	None	None
Short-Term Inhalation (1 to 7 days) (Residential)	Oral study LOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100)	LOC for MOE = 300 (Residential)	Acute Neurotoxicity Study in Rats LOAEL = 2.0 mg/kg/day based on plasma and RBC ChE inhibition in rats; no NOAEL was established.
Intermediate-Term Inhalation (1 week to several months) (Residential)	Oral study LOAEL = 0.2 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 300 (Residential)	13-Week Feeding study in rats LOAEL = 0.2 mg/kg/day based on RBC ChE inhibition in; no NOAEL was established.
Long-Term Inhalation (several months to lifetime) (Residential)	None	None	None
Cancer (oral, dermal, inhalation)	Classified as a Group E chemical, ''not likely'' to be carcinogenic.	None	None

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Coumaphos is an acaricide currently registered for use on livestock animals for the control of arthropod pests. Tolerances have been established (40 CFR 180.189) for the combined residues of coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate) and its oxygen analog, coumaphoxon (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate, in or on meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep, and in milk and eggs. Tolerances are set at 1.0 ppm in livestock tissues, 0.5 ppm in milk-fat residues, and 0.1 ppm in eggs. Although tolerances are still listed in the most recent CFR (revised July 1, 1999) for sheep, goats, and poultry (1.0 ppm) and eggs (0.1 ppm), the use of coumaphos on poultry (eggs) has been canceled and the use of coumaphos on goat and sheep are no longer supported by the technical registrant and will be deleted. Therefore, these commodities are not included in the dietary risk analysis. Risk assessments were conducted by EPA to assess dietary exposures from coumaphos in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®)

analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute analysis for coumaphos is a highly refined (Tier 3 Monte-Carlo) estimate of dietary exposure from residues in food. The following assumptions were made for the acute exposure assessments: use of anticipated residues information for livestock, percent livestock treated information, monitoring data from the USDA PDP program for livestock and monitoring data collected for honey samples treated in 1999 and 2000 under the emergency exemptions from Sioux Honey Association.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The chronic analysis for coumaphos is a refined estimate of dietary exposure from residues in food. The following assumptions were made for the chronic exposure assessments: use of anticipated residues information for livestock, percent livestock treated information, monitoring data from the USDA PDP program for livestock and monitoring data collected for honey samples treated in 1999 and 2000 under the emergency exemptions from Sioux Honey Association.

iii. *Cancer*. Coumaphos is classified as Group E (no evidence of carcinogenicity in humans).

iv. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used the following percent livestock treated (PLT) information: 5% beef (and horse) including lean meat without removable fat, beef fat, beef liver, beef byproducts, kidney; 1% hog including meat, hog fat, hog liver, hog byproducts, and hog kidney; 100% veal including lean meat without removable fat, veal fat, veal liver, veal meat by-products, and veal kidney; and 4% milk. Anticipated residue values (ARs) were calculated from field trial data for estimation of both acute and chronic dietary exposure for all livestock commodities, with the exception of milk. The residue values used for milk are from the USDA's PDP 1997 and 1998 monitoring data which show no detectable residues in milk out of 750 samples tested. Anticipated residues used for honey were based on monitoring data provided by Sioux Honey Association. These data represent raw honey samples which were likely to be treated under Section 18 exemptions in 1999 and 2000. Only those samples with detectable or quantifiable residues (limit of detection = 1 ppb) of coumaphos (parent) were included in the anticipated residue calculations. Some samples were analyzed more than once. In those cases the average value of the multiple analyses was used to calculate the residue level for chronic exposure, whereas the highest value was chosen for the acute analysis.

The Agency believes that the three conditions listed in Unit IV.B.1.iv. of this preamble have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which coumaphos may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure 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 physical characteristics of coumaphos.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1

model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to coumaphos they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of coumaphos in surface water and ground water, respectively, for acute exposures are estimated to be 1.9 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. Note, in the Revised Risk Assessment for Coumaphos, released by the Agency as published in the **Federal Register** of April 26, 2000 (65 FR 24468) (FRL–6556–7), with the comment period ending June 26, 2000, the estimated EECs for surface and ground water are different than those reported above. Based on the available environmental data, the K_{oc} value for the parent coumaphos is 3,994 to 11,422. In the Revised Risk Assessment for Coumaphos, in absence of data on the degradate coumaphoxon, it was assumed that the K_{oc} value for coumaphoxon was 0.1. Therefore, the EECs values represented an overly conservative exposure assessment. For this risk assessment the Agency used a computer estimation program (EPI version 3.04) to estimate a more realistic K_{oc} value of 92.3 and water solubility value of 31.61 at 25°C for coumaphoxon. Use of these values accounts for the difference in estimated EECs. Furthermore, Bayer Corporation recently provided preliminary results of data conducted on coumaphoxon that indicate that the K_{oc} values for coumaphoxon are 1,897.78 and greater. Finally, the Agency has recently received information that suggests that most of the coumaphos residual resulting from dip use on livestock is collected and transported to concrete-lined evaporation pits thereby negating any potential for ground water contamination. The Agency is currently verifying these practices. For these reasons the revised EECs are still considered a very conservative exposure assessment.

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 exposure to substances with a common mechanism of toxicity.* In applying the safety standard in section 408(b)(2)(A), EPA is required to consider, among other relevant factors, ''available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity.'' Coumaphos is in a family of pesticides known as organophosphates. As documented in EPA presentations to the FIFRA Scientific Advisory Panel, EPA has concluded that organophosphates share a common mechanism of toxicity and thus have a cumulative toxic effect (A Common Mechanism of Action: The Organophosphate Pesticides, 11/2/98, USEPA). Based on this conclusion EPA has been working toward preparing a cumulative risk assessment on the organophosphate pesticides, including coumaphos, as part of the tolerance reassessment program and has generally refused to register new uses of organophosphates under FIFRA or establish new tolerances for such pesticides under the FFDCA prior to completing this cumulative assessment. EPA has considered the potential cumulative effects of coumaphos. EPA has concluded the risks posed by granting this tolerance are so small that they are effectively indistinguishable from the overall aggregate risk of coumaphos, much less the overall cumulative risk posed by the organophosphates. The dire need for this use, combined with its infinitesimal risk, make it clear, that no matter what the result of any cumulative risk assessment for the organophosphates, it is very unlikely that this use would be proposed for revocation.

C. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies.* The developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity to young rats or rabbits following prenatal or postnatal exposure to coumaphos and comparable NOAELs were established for adults and offspring.

In a developmental toxicity study pregnant rats received oral doses of coumaphos at 0, 1, 5 or 25 mg/kg/day during gestation days 6 through 15. For maternal toxicity, the NOAEL was 5 mg/kg/day and the LOAEL was 25 mg/kg/day based on clinical signs of cholinesterase inhibition. For developmentaltoxicity, the NOAEL was 25 mg/kg/day (HDT); a LOAEL was not established. There was no evidence of teratogenicity.

In a developmental toxicity study, pregnant rabbits were given single oral dose of coumaphos at 0, 0.25, 2, or 18 mg/kg/day during gestation days 7 through 19. For maternal toxicity, the NOAEL was 2 mg/kg/day and the LOAEL was 18 mg/kg/day based on mortality (2/17) and cholinergic signs. For developmental toxicity, the NOAEL was 18 mg/kg/day (HDT); a LOAEL was not established. There was no evidence of teratogenicity.

3. *Reproductive toxicity study.* In a 2–generation reproduction study, rats were

fed diets containing coumaphos at 0, 0.07, 0.3, or 1.79 mg/kg/day in males and 0, 0.08, 0.34 or 2.02 mg/kg/day in females, respectively. There was no increased sensitivity to pups over the adults. For parental/systemic toxicity, the NOAEL was 1.79 mg/kg/day, (HDT); a LOAEL was not established. For reproductive toxicity, the NOAEL was 1.79 mg/kg/day; a LOAEL was not established.

4. *Cholinesterase inhibition*. Cholinesterase activity was not measured in the adults and offspring in the developmental toxicity studies. In the reproduction study, ChE activity was measured in adults and pups. There was dose-related decreases in plasma and red blood cell cholinesterase activity in dams at 0.34 and 2.02 mg/kg/day. Generally, no differences were seen on day 47 and day 91 measurements. Brain levels were biologically significantly inhibited in F_0 and F_1 adult females at 2.02 mg/kg/day, and in F_0 adult males at 1.79 mg/kg/day. In pups, no significant changes in red blood cell or brain cholinesterase activity were seen on day 4, but on day 21 changes were seen at 2.02 mg/kg/day. In F_1 pups, plasma and red blood cell ChE inhibition of 38–44% was seen, while in F_2 pups, only plasma was affected (31–44%). The only significant brain inhibition in pups was an 8% decrease in F_1 females on day 21. The NOAEL was 0.3 for cholinesterase inhibition in dams and in pups on day 21.

5. *Neurotoxicity*. In an acute delayed neurotoxicity study, no delayed neurotoxicity was seen in hens given a single oral dose (via gelatin capsule) of coumaphos at 50 mg/kg. There are sufficient data available to adequately assess the potential for toxicity to young animals following prenatal and/or postnatal exposure to coumaphos. These include acceptable developmental toxicity studies in rats and rabbits, as well as, a 2–generation reproduction studies in rats. In addition, no treatment-related neuropathology was seen after acute and subchronic exposure to rats. Additionally, there was no evidence of abnormalities to the fetus to the fetal nervous system in the prenatal and postnatal studies.

6. *Prenatal and postnatal sensitivity*. Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to coumaphos. There was no indication of increased susceptibility in the offspring as compared to parental animals in the 2–generation reproduction study. In these studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

7. *Conclusion*. Previously for coumaphos, the Agency recommended the FQPA safety factor be reduced from 10x to 3x due to data gaps for the acute and subchronic neurotoxicity studies. These data requirements have been satisfied and therefore, the Agency has determined the FQPA safety factor can be reduced to 1x. The decision to reduce the FQPA Safety factor to 1x is based on the following:

The previous data gap for acute and subchronic neurotoxicity have been satisfied. There is no indication of increased susceptibility of rat or rabbits to coumaphos. In the developmental and reproduction toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day)= cPAD—(average food+ chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to coumaphos in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of coumaphos on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to coumaphos at the 99.9th percentile will occupy 8% of the aPAD for the U.S. population, 4% of the aPAD for females 13 through 50 years old, 21% of the aPAD for all infants less than 1 year old, the infant subpopulation at greatest exposure and 15% of the aPAD for children 1–6 years old, the children subpopulation at greatest exposure. In addition, despite the potential for acute dietary exposure to coumaphos in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of coumaphos in surface and ground water. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO COUMAPHOS

Population subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.007 mg/kg/day	8 %	1.9	0.17	220
Females, 13–50 years old	0.007	4 %	1.9	0.17	200
All Infants, less than 1 year old	0.007 mg/kg/day	2 1%	1.9	0.17	54

AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO COUMAPHOS—Continued

Population subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
Children, 1–6 years old	0.007 mg/kg/day	15%	1.9	0.17	59

Comparing the risk estimates for the addition of honey and beeswax to those discussed in the risk assessment recently released for public comment under Phase 5 of the reregistration process for the registered uses on livestock, the Agency concludes that there is no incremental increase in dietary exposure or risk when the residues in honey are added to those from the registered uses on livestock. The slight changes reported in some cases (e.g., increase in acute exposure for children 7–12 years old) are likely to be within the noise or uncertainty of the analyses. The fact that the calculated exposure actually decreases in a few cases when honey is added to livestock is further indication of this.

COMPARISON OF AGGREGATE RISK FOR ACUTE EXPOSURE TO COUMAPHOS WITHOUT AND WITH HONEY

Population subgroup	Acute exposure without honey (mg/kg/day)	Acute exposure with honey (mg/kg/day)	Percent acute PAD without honey	Percent acute PAD with honey
U.S. Population	0.000528	0.000524	7.55%	7.49%
Females, 13–50 years old	0.000247	0.000247	3.52%	3.53%
All Infants, less than 1 year old	0.001494	0.001493	21.34%	21.33%
Children, 1–6 years old	0.001069	0.001069	15.27%	15.27%
Children, 7–12 years old	0.000520	0.000524	7.42%	7.49%

Within the operating capability of the model, the Agency concludes that the above results show there is no incremental increase in dietary exposure or risk when the residues in honey are added to those from the registered uses on livestock.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to coumaphos from food will utilize 6% of the cPAD for the U.S. population, 4% of the cPAD for all infants less than 1 year old, and 14 % of the cPAD for children 1–6 years old, the children subpopulation at greatest exposure. There are no residential uses for coumaphos that result in chronic residential exposure to coumaphos. In addition, despite the potential for chronic dietary exposure to coumaphos in drinking water, after calculating the DWLOCs and comparing them to conservative model estimated environmental concentrations of coumaphos in surface and ground water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO COUMAPHOS

Population subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0003	6%	0.41	0.17	10
All Infants, less than 1 year old	0.0003	4%	0.41	0.17	3
Children, 1–6 years old	0.0003	14%	0.41	0.17	9

Comparing the risk estimates for the addition of honey and beeswax to those discussed in the risk assessment recently released for public comment under Phase 5 of the reregistration process for the registered uses on livestock, the Agency concludes that there is no incremental increase in dietary exposure or risk when the residues in honey are added to those from the registered uses on livestock. The slight changes reported in some cases are likely to be within the noise or uncertainty of the analyses. The fact that the calculated exposure actually decreases in a few cases when honey is added to livestock is further indication of this.

COMPARISON OF AGGREGATE RISK FOR CHRONIC EXPOSURE TO COUMAPHOS WITHOUT AND WITH HONEY

Population Subgroup	Chronic exposure without honey (mg/kg/day)	Chronic exposure with honey (mg/kg/day)	% Chronic PAD without honey	% Chronic PAD with honey
U.S. Population	0.000013	0.000013	5.3%	5.4%
Females, 13–50 years old	0.000009	0.000009	3.7%	3.7%
All Infants, less than 1 year old	0.000011	0.000011	4.3%	4.3%
Children, 1–6 years old	0.000033	0.000033	13.2%	13.2%
Children, 7–12 years old	0.000022	0.000022	8.9%	8.9%

Within the operating capability of the model, the Agency concludes that the above results show there is no incremental increase in dietary exposure or risk when the residues in

honey are added to those from the registered uses on livestock.

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). 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, which were previously addressed.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational 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, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. Coumaphos is classified as Group E (no evidence of carcinogenicity in humans).

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 coumaphos residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (LC/MS/MS) is available to enforce the tolerance expression. The method for honey is Bayer Method 150.803 and for beeswax is Bayer Method 150.804. Either method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex tolerances for coumaphos, therefore there are no harmonization issues with this tolerance.

VI. Conclusion

Therefore, the tolerances are established for combined residues of coumaphos, (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate) and its oxygen analog, coumaphoxon (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphate, in or on honey at 0.1 ppm and beeswax at 100 ppm.

VII. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301039 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 October 16, 2000.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301039, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not

include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review 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 FIFRA section 18 petition under FFDCA section 408, such as the tolerances 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 FFDCA section 408(n)(4).

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: August 3, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.189 is amended by adding text to paragraph (b) to read as follows:

§ 180.189 Coumaphos; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions*. Time–limited tolerances are established for the combined 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 connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Beeswax	100 ppm	12/31/02
Honey	0.1 ppm	12/31/02

* * * * *

[FR Doc. 00–20732 Filed 8–15–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301029; FRL–6598–9]

RIN 2070–AB

Zinc Phosphide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on barley and wheat grain, hay and straw and wheat aspirated grain fractions. This action is in response to EPA's