List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 4, 2008.

Lois Rossi,

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 180.940 is amended by alphabetically adding entries to the table in paragraph (a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * * * *	* *	
Amylopectin, acid-hydrolyzed, 1-oxtenylbutanedioate	113894–85–2	none
Amylopectin, hydrogen 1-octadecenylbutanedioate	125109–81–1	none
* * * * *	* *	

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■ 3. Section 180.950 is amended by alphabetically adding entries to the table in paragraph (e) to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical	CAS No.
* *	* * *
Amylopectin, acid-hydrolyzed, 1-octenylbutanedioate	113894–85–2
Amylopectin, hydrogen 1-octadecenylbutanedioate	125109–81–1
* *	* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0894; FRL–8382–6]

Ethoprop; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethoprop in or on hop, dried cones; peppermint, tops; and spearmint, tops. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 17, 2008. Objections and requests for hearings must be received on or before November 17, 2008, 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–2007–0894. All documents in the docket are listed in the docket index available at *http://www.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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 electronically available documents 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 FFDCA, 21 U.S.C. 346a, 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–2007–0894 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 November 17, 2008.

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–2007–0894, 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 Facility'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 September 28, 2007 (72 FR 55204) (FRL–8147–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 5E4491 and PP 7E7247) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201, Princeton, NJ 08540. The petitions requested that 40 CFR 180.262 be amended by establishing tolerances for residues of the insecticide and nematicide, ethoprop, *O*-ethyl *S,S*-dipropyl phosphorodithioate, in or on hop, dried cone (PP7E7247) and mint, hay (PP 5E4491) at 0.02 parts per million (ppm). That notice referenced a summary of the petitions prepared by Bayer CropScience, the registrant, on behalf of IR-4, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

IR-4 proposed a tolerance on the commodity ''mint, hay'' at 0.02 ppm. EPA has determined that separate tolerances at 0.02 ppm should be established on the commodities ''spearmint, tops'' and ''peppermint, tops'' instead of the single tolerance on ''mint, hay'' to agree with the preferred commodity terms in the Agency's Food and Feed Commodity Vocabulary. EPA has also modified the commodity term ''hop, dried cone'' slightly to read ''hop, dried cones'' to agree with the Food and Feed Commodity Vocabulary.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of ethoprop on hop, dried cones; peppermint, tops; and spearmint, tops at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxic mode of action of ethoprop in insects and humans is by phosphorylation of the acetylcholinesterase (referred to as cholinesterase or ChE in this document) enzyme in the brain and peripheral nervous systems. The resulting enzyme inhibition causes accumulation of the neurotransmitter, acetylcholine, and resulting signs of neurotoxicity.

Ethoprop is acutely toxic by both oral and dermal routes. In the longer term studies, the most sensitive indication of toxicity was inhibition of brain and red blood cell (RBC) ChE. Signs of neurotoxicity related to inhibition of ChE by ethoprop include tremors, ataxia, muscle fasiculations, lacrimation, salivation, rapid/shallow respiration, repetitive chewing movements, nasal and perianal stains, vocalization, aggressive behavior, decreased grip strength, and decreased motor activity. A slight anemia and liver toxicity (elevated liver enzymes and microscopic liver lesions) were also noted in dog studies.

Ethoprop is classified ''likely to be carcinogenic to humans'' based on malignant adrenal pheochromocytomas in male rats and is regulated by EPA using the linear low dose extrapolation approach with a potency factor (Q_1*) of 2.81×10^{-2} milligrams/kilogram/day $(mg/kg/day)^{-1}$.

No developmental toxicity was noted in rat and rabbit developmental studies. In the rat developmental toxicity study, maternal toxicity included decreased body weight gain and increased incidence of soft stool, the latter effect attributed to ChE inhibition. No maternal toxicity occurred in the rabbit developmental study. Despite the absence of toxicity in this study, dosing was considered adequate, since the highest dose was close to the lethal dose determined in the range-finding developmental rabbit study. Ethoprop did not affect reproductive parameters in the 2-generation reproduction toxicity study in rats. Pup mortality in this study occurred at a high dietary concentration and was accompanied by significant maternal toxicity (clinical signs of tremors and loose stool and brain ChE inhibition).

In the developmental neurotoxicity (DNT) study, an effect on learning in the water maze test was noted in high-dose males. Motor activity in all male treatment groups was increased on postnatal day 17 due to a lack of habituation (i.e., there was little or no decrease in activity over the course of the test session). There was no indication of increased fetal or offspring sensitivity to ChE inhibition in this study.

The relative sensitivities of adult rats and 11–day old rat pups to ChE

inhibition were compared in acute and 11–day comparative cholinesterase studies. Pups were 8 times as sensitive as adults for brain ChE inhibition in the acute study and were 12 times as sensitive as adults in the 11–day study. Pup sensitivity is believed to be due to their immature metabolic capacity.

Specific information on the studies received and the nature of the adverse effects caused by ethoprop, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies, can be found at *http://www.regulations.gov* in the document *Ethoprop Human Health Risk Assessment of New Uses on Hops and Mint* at page 47 in docket ID number EPA–HQ–OPP–2007–0894.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (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 adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for ethoprop used for human risk assessment can be found at *http://www.regulations.gov* in the document *Ethoprop Human Health Risk Assessment of New Uses on Hops and Mint* at page 20 in docket ID number EPA–HQ–OPP–2007–0894.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to ethoprop, EPA considered exposure under the petitioned-for tolerances as well as all existing ethoprop tolerances in 40 CFR 180.262, except peanuts. Although tolerances for peanuts and peanut hay have been established, there have been no active registrations for use of ethoprop on peanuts since April, 2002, and the Agency proposed to revoke the peanut tolerances in the **Federal Register** of June 4, 2008 (73 FR 31788) (FRL–8363–9). For these reasons, peanuts were not considered in the dietary assessment.

The residues of concern for acute and chronic dietary risk assessment include parent ethoprop and the metabolites S-ME, *O*-ethyl-*S*-methyl-*S*-propylphosphorodithioate, and O-ME, *O*-ethyl-*O*-methyl-*S*-propylphosphorothioate. For cancer dietary risk, the residues of concern are parent and the metabolites S-ME-, O-ME and M-1, *O*-ethyl-*S*-propyl phosphorodithioate. Since the available field trial and monitoring data do not include information on the metabolites, metabolite ratios derived from metabolism and rotational crop studies were used to estimate metabolite levels in ethoprop-treated commodities. Further information on the development of the metabolite ratios can be found at *http://www.regulations.gov* in the document *Ethoprop. Anticipated Residues to Support New Uses on Hops and Mint* in docket ID number EPA–HQ–OPP–2007–0894. EPA assessed dietary exposures from the combined residues of ethoprop and its metabolites of concern in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA relied on anticipated residues derived from field trials or monitoring data from USDA's Pesticide Data Program (PDP) for most commodities. PDP data were used to develop anticipated residues for bananas, snap beans (fresh and canned), corn syrup, cucumber, pineapple, potato and sweet potato. Field trial data were used for field corn, sweet corn, sugarcane and cabbage. EPA assumed tolerance-level residues for lima beans and the new commodities, hops and mint. Acute dietary exposure estimates were further refined using maximum percent crop treated (PCT) estimates for snap beans, cabbage, sweet corn, field corn, cucumber, potatoes, sugarcane and sweet potato. EPA assumed 100 PCT for bananas, lima beans, pineapple, hops and mint.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA relied on anticipated residues derived from field trials or PDP monitoring data for the same commodities specified above under ''*Acute exposure*.'' Again, EPA assumed tolerance-level residues for lima beans, hops and mint. Chronic dietary exposure estimates were further refined using average percent crop treated (PCT) estimates for snap beans, cabbage, sweet corn, field corn, cucumber, potatoes, sugarcane and sweet potato. EPA assumed 100 PCT for bananas, lima beans, pineapple, hops and mint.

iii. *Cancer*. Cancer risk was assessed using the linear low dose extrapolation approach with a potency factor (Q1*) of 2.81×10^{-2} $(mg/kg/day)^{-1}$. In conducting the cancer dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII and the same field trial/PDP monitoring data and PCT data used in the chronic assessment. Different metabolite ratios were used, since the metabolites of concern for cancer risk differ from the metabolites of concern for chronic risk.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of 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 require pursuant to FFDCA section 408(f)(1) 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Acute dietary exposure assessment: Snap beans 5%; cabbage 5%; sweet corn 5%; field corn 2.5%; cucumber 5%; potatoes 5%; sugarcane 5%; and sweet potato 15%.

Chronic and cancer dietary exposure assessments: Snap beans 5%; cabbage 5%; sweet corn 1%; field corn 1%; cucumber 1%; potatoes 5%; sugarcane 5%; and sweet potato 15%.

In most cases, EPA uses available data from the United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable information on the regional consumption of food to which ethoprop may be applied in a particular area.

2. *Dietary exposure from drinking water*. Concerns about the potential for ethoprop or its metabolites to reach water used for drinking water at levels of concern were identified in the *''Interim Reregistration Eligibility Decision for Ethoprop''*, published in September, 2001 and available on the Office of Pesticide Programs' web site at *http://www.epa.gov/pesticides/reregistration/status.htm*. EPA's concerns were based on screening drinking water assessments conducted using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, which indicated potential drinking water concentrations above EPA's levels of concern for acute and cancer exposures. As a result of these concerns, the registrant was required by the Agency to conduct targeted monitoring surveys of presumed high vulnerability community water supplies to determine concentrations of ethoprop that may occur in ground water and surface water. The monitoring data required by EPA have been submitted and reviewed and demonstrate considerably lower water concentrations of ethoprop than the modeled values (by more than 2 orders of magnitude). Although the monitoring surveys do not reflect the new uses on hops and mint, EPA does not expect the new uses to contribute substantially to high-end ethoprop drinking water exposure, since both of the proposed use sites are of minor acreage, and the production regions do not correspond to the areas that were found to be at greatest risk for drinking water exposure. Therefore, EPA believes the monitoring survey results represent reasonable estimates of ethoprop residues likely to occur in drinking water from all existing and new uses. Although the highest measured values from the monitoring surveys do not represent the peak concentrations that could occur in drinking water, the theoretical peak is highly likely to be much closer to the monitoring values than the modeled values, in part because the usage intensity (i.e., pounds active ingredient per acre) assumed by the model is 250 to 500 times the highest actual watershed-wide usage intensity estimated in the monitoring study; and sales data recently submitted by the registrant show that ethoprop usage has gradually declined nationwide since the drinking water study was completed. Therefore, the Agency relied on the monitoring survey data in assessing drinking water exposures to ethoprop and its degradates of concern as described below.

The sum of the highest concentrations of ethoprop and its drinking water degradates of concern (S-ME; O-ME; O-HE, *O*-ethyl-*S*-propylphosphorothioate; and SSDP, *S,S*-dipropylphosphorodithioate) measured in the targeted monitoring surveys was 0.231 parts per billion (ppb). This water concentration value was directly entered into the dietary exposure model and used to assess acute, chronic and cancer drinking water exposures to ethoprop. Recognizing that this value does not represent the theoretical peak ethoprop drinking water concentration, EPA conducted additional acute, chronic and cancer dietary analyses using a drinking water concentration of 0.52 ppb, equivalent to more than 2x the highest measured monitoring value. For the drinking water exposure scenarios of greatest concern (acute and cancer), EPA also conducted analyses using the highest drinking water concentration that would result in aggregate risks below the level of concern: 15 ppb (65x the highest monitoring value) for the acute assessment and 5 ppb (22x the highest monitoring value) for the cancer assessment.

EPA notes that the highest measured concentrations of ethoprop used in the dietary assessment occurred in raw water and, therefore, do not account for

any mitigation of exposure that might occur as a result of water treatment. The registrant did analyze finished water on dates for which raw water bore detectable residues, and the concentrations in finished water were generally lower than those in raw water samples taken on the same day.

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).

Ethoprop is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' 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. Ethoprop 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 Pesticide Data Program (PDP) and dietary consumption data collected by USDA's 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 at *http://www.ams.usda.gov/science/pdp*. No PDP data on mint or hops currently exist that could have been used in a cumulative assessment. OP residues in hops and mint were not included in the PDP database, in part because hops and mint are low-consumption foods. A quantitative estimate of mint 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. The maximum consumption estimate at the 99.9th percentile of exposure for all populations is less than 0.1 grams mint/day. Hops are used when brewing beer, and there can be relatively high consumption of beer in some population groups. However, the relative amount of hops used in brewing beer, on a weight basis, is low, so hops consumption is low as well.

EPA does not believe that inclusion of ethoprop residues in hops and mint in the OP CRA will significantly modify the calculated risk. First, hops and mint are low consumption foods, and, thus, even if hops and mint contained quantifiable levels of OPs, it would be unlikely to significantly alter the OP CRA. Secondly, residues of ethoprop in hops and mint are non-detectable at the label application rate, based on controlled crop field trials. Also, there is virtually no difference in ethoprop exposure when hops and mint are excluded from the dietary exposure assessment. If ethoprop exposure from hops and mint is insignificant in comparison to exposure to ethoprop 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 ethoprop hops and mint tolerances will not raise a concern regarding cumulative OP exposure.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The following acceptable studies are available for assessing potential sensitivity of infants and children to ethoprop: Rat and rabbit developmental toxicity studies, a DNT study in rats, a 2-generation reproduction toxicity study in rats, acute and subchronic neurotoxicity studies, an acute comparative cholinesterase study in adult and rat pups, and an 11–day comparative cholinesterase study in adult and rat pups. There was no evidence of increased quantitative or qualitative susceptibility to ethoprop of *in utero* rats or rabbits in the developmental toxicity studies and no evidence of increased susceptibility of fetuses or offspring in the DNT study. In the DNT study the NOAEL for brain ChE activity in pups was the same as for adults and the NOAEL for RBC ChE activity was greater in pups than for adults. Fetuses were less sensitive to ChE inibition by ethoprop than were the adults.

Pup mortality in the 2-generation reproduction study occurred at a high dietary concentration and was accompanied by significant maternal toxicity (clinical signs of tremors and loose stool and brain ChE inhibition).

The NOAEL for pup mortality was 13 mg/kg/day. Because the POD for chronic dietary exposure (0.14 mg/kg/day) is much lower than the NOAEL for pup mortality and is protective of this endpoint, there are no residual concerns for sensitivity to infants and children from this study.

In the acute comparative cholinesterase study, pups were eight times as sensitive as adults for brain ChE inhibition. This study was used to select a POD for acute dietary assessment. Because the POD is protective of the population of concern, there are no residual concerns from this study.

In the 11–day comparative cholinesterase study, pups were 12 times as sensitive as adults for brain ChE inhibition. This study was used to select a POD for chronic dietary assessment. Because the POD is protective of the population of concern, there are no residual concerns from this study.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for ethoprop is complete, except for immunotoxicity studies. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect well after the tolerance petitions were submitted, these studies are not yet available for ethoprop. In the absence of specific immunotoxicity studies, EPA has evaluated the available ethoprop toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. Ethoprop does not belong to a class of chemicals that would be expected to be immunotoxic; however, there was some indication of possible immunotoxicity in the form of decreased white blood cell counts in high-dose males (4 mg/kg/day) in the mouse carcinogenicity study. Since the dose at which this effect was seen is nearly 30 times higher than the BMDL10 of 0.14 mg/kg/day already established for ethoprop, and since there was no other evidence of immunotoxicity in the ethoprop toxicity studies, EPA does not believe that conducting immunotoxicity testing will result in a lower POD for ethoprop, and an additional database uncertainty factor for ethoprop is not needed to account for potential immunotoxicity.

ii. Ethoprop is a neurotoxic chemical. Although there is evidence in the acute and 11–day comparative cholinesterase studies of increased offspring senstivity to ChE inhibition by ethoprop, there are no residual uncertainties with regard to these effects in infants and children. The points of departure for acute and chronic dietary assessment are based on brain ChE inhibition in pups in the comparative cholinesterase studies. Benchmark dose (BMD) modeling was used to select points of departure for dietary exposure. In comparison to other toxicity studies, the comparative cholinesterase studies had much closer dose spacing around the NOAEL and LOAEL doses and thus provided an accurate determination of BMDL10 values (the lower 95% confidence limit on the estimated mean brain ChE inhibition 10% effect level) used to evaluate risk. Furthermore, since the comparative cholinesterase studies provided an assessment of comparative sensitivity of adults and offspring; and provided the lowest, most sensitive points of departure for the most vulnerable population, the points of departure based on these studies are protective of other toxic effects.

iii. There is no evidence that ethoprop results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. Although there is some evidence of increased qualitative susceptibility of offspring in the 2-generation reproduction study (pup mortality vs. clinical signs of tremors, loose stool and brain ChE inhibition in maternal animals), the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments utilized anticipated residues that are based on reliable field trial or monitoring data. For most currently registered commodities, the dietary assessments also utilized PCT data that have a valid basis and are considered to be reliable. The drinking water exposure assessments utilized targeted monitoring data from vulnerable community raw water supplies intended to provide reasonably conservative (i.e., high-end) estimates of drinking water concentrations. To account for the possibility of higher drinking water concentrations than those measured in the monitoring surveys, EPA utilized concentrations from 2x to 65x the highest measured value in the dietary exposure assessments. Residential exposure to ethoprop is not expected to occur. These assessments will not underestimate the exposure and risks posed by ethoprop.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the food exposure assumptions discussed in this unit for acute exposure and the highest measured concentrations of ethoprop and its degradates from the targeted drinking water monitoring surveys (0.231 ppb), the acute dietary exposure from food and water to ethoprop will occupy 18% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure. Using a drinking water estimate for ethoprop and its degradates of 0.52 ppb, equivalent to more than 2x the maximum measured value from monitoring data, acute dietary exposure to ethoprop from food and water will occupy 19% of the aPAD for infants less than 1 year old. These acute dietary risk estimates are based on high-end exposures at the 99.9th percentile.

2. *Chronic risk*. Using the food exposure assumptions described in this unit for chronic exposure and the highest measured concentrations of ethoprop and its degradates from the targeted drinking water monitoring surveys (0.231 ppb), EPA has concluded that chronic exposure to ethoprop from food and water will utilize 2.7% of the cPAD for infants less than 1 year old and children 1 to 2 years old, the population groups receiving the greatest exposure. Using a drinking water estimate for ethoprop and its degradates of 0.52 ppb, equivalent to more than 2x the maximum measured value, chronic dietary exposure to ethoprop from food and water will occupy 4.2% of the cPAD for infants less than 1 year old and 3.4% for children 1 to 2 years old. There are no residential uses for ethoprop.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposures take into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Ethoprop is not registered for any use patterns that would result in residential exposure. Therefore, the short-term or intermediate-term aggregate risk is the sum of the risk from exposure to ethoprop through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* Using the food exposure assumptions described in this unit for the cancer risk assessment and the highest measured concentrations of ethoprop and its degradates from the targeted drinking water monitoring surveys (0.231 ppb), EPA has concluded that exposure to ethoprop from food and water will result in a lifetime cancer risk of 4×10^{-7} for the U.S. population. EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. Residues of ethoprop and its degradates of concern in drinking water could be as high as 5 ppb (22x the highest measured monitoring value) before lifetime cancer risk exceeded this level.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ethoprop residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Two gas chromatography (GC)/sulfur microcoulometric detection methods are available in the Pesticide Analytical Methods, Volume II (Methods I and A). Both involve solvent extraction and clean-up by sweep co-distillation and have a reported limit of quantitation (LOQ) of 0.01 ppm for most commodities.

B. International Residue Limits

There are no Canadian, CODEX or Mexican Maximum Residue Limits established for residues of ethoprop on mint or hops.

V. Conclusion

Therefore, tolerances are established for residues of ethoprop, *O*-ethyl *S,S*-dipropyl phosphorodithioate, in or on hop, dried cones; peppermint, tops; and spearmint, tops at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *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 9, 2000) do not apply to this final rule. In addition, this final 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) (Public Law 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), Public Law 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: September 8, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.262 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.262 Ethoprop; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Hop, dried cones	0.02
* * *	* *
Peppermint, tops	0.02
* * *	* *
Spearmint, tops	0.02
* * *	* *

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[FR Doc. E8–21589 Filed 9–16–08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0674; FRL–8375–2]

2,4-D, Bensulide, Chlorpyrifos, DCPA, Desmedipham, Dimethoate, Fenamiphos, Metolachlor, Phorate, Sethoxydim, Terbufos, Tetrachlorvinphos, and Triallate; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking certain tolerances for the herbicides metolachlor and sethoxydim and the insecticides chlorpyrifos, dimethoate, fenamiphos, terbufos, and tetrachlorvinphos. Also, EPA is modifying certain tolerances for the herbicides 2,4-D, DCPA, desmedipham, metolachlor, sethoxydim, and triallate and the insecticides chlorpyrifos, dimethoate, fenamiphos, phorate, and tetrachlorvinphos. In addition, EPA is establishing new tolerances for the herbicides bensulide, metolachlor, and sethoxydim and the insecticide chlorpyrifos. The regulatory actions finalized in this document are in follow-up to the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and tolerance reassessment program under the Federal Food, Drug, and Cosmetic Act (FFDCA), section 408(q).

DATES: This regulation is effective September 17, 2008. Objections and requests for hearings must be received on or before November 17, 2008, 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–2007–0674. All documents in the docket are listed in the docket index available at *http://www.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: Jane Smith, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0048; e-mail address: *smith.jane-scott@epa.gov@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 436a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0674 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 17, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0674, 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 Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

A. What Action is the Agency Taking?

In the **Federal Register** of February 6, 2008 (73 FR 6867) (FRL–8345–2), August 8, 2007 (72 FR 44439) (FRL–8138–8), and May 23, 2007 (72 FR 28912) (FRL–8130–8), EPA issued proposals to revoke, modify, and establish specific tolerances for residues