ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0221; FRL–7199–2]

Dimethomorph; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dimethomorph in or on hop, dried cones at 60 parts per million (ppm); lettuce, leaf and lettuce, head at 10 ppm; vegetable, cucurbit, group at 0.5 ppm; and vegetable, bulb, group at 2.0 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0221, must be received on or before November 26, 2002.

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 VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0221 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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	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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0221. 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, Crystal 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

In the **Federal Register** of August 21, 2002 (67 FR 54192) (FRL–7191–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 0E6178, 2E6386, 2E6410, 2E6432) by IR-4, 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390. This notice included a summary of the petitions prepared by BASF Corporation, Research Triangle Park, NC., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.493 be amended by establishing tolerances for residues of the fungicide dimethomorph, [[(E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine]], in or on the following food commodities:

1. PP 0E6178 proposed a tolerance for hop, dried cones at 60 ppm. This tolerance replaces the existing tolerance for hops, cones, dried at 60 ppm. There were no U.S. registrations for use of dimethomorph on hops when the existing tolerance was established. IR-4 provided magnitude of residue studies and has requested a new tolerance for hop, dried cones at 60 ppm in support of U.S. registration for hops.

2. PP 2E6386 proposed a tolerance for lettuce, leaf and lettuce, head at 10 ppm.

3. PP 2E6410 proposed a tolerance for vegetable, cucurbit, group at 0.5 ppm.

4. PP 2E6432 proposed a tolerance for vegetable, bulb, group at 2.0 ppm.

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....''

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of dimethomorph on hop, dried cones at 60 ppm; lettuce, leaf and lettuce, head at 10 ppm; vegetable, cucurbit, group at 0.5 ppm; and vegetable, bulb, group at 2.0 ppm. EPA's assessment of exposures and risks associated with establishing the 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 nature of the toxic effects caused by dimethomorph are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL = 73 milligrams/kilogram/day (mg/kg/day) for males, and 82 mg/kg/day for females. A LOAEL was not established, because the highest dose tested produced no biologically significant effect.
870.3150	90–Day oral toxicity in nonrodents	NOAEL = 15 mg/kg/day LOAEL = 43 mg/kg/day based on a decrease in the absolute and relative weights of the prostate and possible threshold liver effects (increased alkaline phosphatase activity at weeks 6 and 13).
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 60 mg/kg/dayLOAEL = 160 mg/kg/day based on based on decreased mean body weight on gestation days 10–15; decreased body weight gain on gestation days 10–15, decreased food consumption days 6–15 .Developmental NOAEL = 60 mg/kg/dayLOAEL = 160 mg/kg/day based on increased resorptions.
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 300 mg/kg/day LOAEL = 650 mg/kg/day based on decreased body weights and body weight gain. Developmental NOAEL = 650 mg/kg/day. No developmental toxicity was observed in this study.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 20.8 mg/kg/day in males and 24 mg/kg/day in females. LOAEL = 69 mg/kg/day for males and 79.3 mg/kg/day for females based on decreased body weights and body weight gain. Reproductive NOAEL = 69 mg/kg/day for males and 79.3 mg/kg/day for females (highest dose tested). Offspring NOAEL = 20.8 mg/kg/day for males and 24 mg/kg/day for females. LOAEL = 69 mg/kg/day for males and 79.3 mg/kg/day for females based on delayed incisor eruption at day 10 postpartum.
870.4100	Chronic toxicity rodents	NOAEL = 11.9 mg/kg/day for females and 36.2 mg/kg/day for males.LOAEL = 57.7 mg/kg/day for female rats based on decreased body weight and a significant increase in the incidence of ground glass foci in the liver, and 99.9 mg/kg/day for male rats based on decreased body weight and increased incidence of arteritis.
870.4100	Chronic toxicity dogs	NOAEL = 14.7 mg/kg/day for males and 15.7 mg/kg/day for females. LOAEL = 44 mg/kg/day for males and 47 mg/kg/day for females based on based on decreased prostate weight in males.
870.4200	Carcinogenicity rats	NOAEL = 33.9 mg/kg/day for males and 11.4 mg/kg/day for females. LOAEL = 94.6 mg/kg/day for males and 46.3 mg/kg/day for females based on decreased body weight gain.The test material had no significant effect on the development of neoplasms in male or female rats at the doses tested. Dimethomorph was tested at adequate doses based on significant decreases in body weight (17% and 13%) and body weight gains (27% and 14%) in females and males, respectively, in the high dose groups.
870.4300	Carcinogenicity mice	There were no treatment-related increases in the incidence of any neoplastic lesions. The chemical was adequately tested based on decreased body weight gain at 1,000 mg/kg/day. The NOAEL for systemic toxicity is 100 mg/kg/day.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
	Gene Mutation/Cytogenetics/Other Effects	Dimethomorph did not cause gene mutations in *Salmonella* or *E. coli* bacterial strains, as well as in mammalian gene mutation studies. It was negative for structural chromosomal aberrations in the mouse micronucleus assay at up to 5,000 mg/kg after oral treatment, and up to 200 mg/kg when administered intraperitoneally. However, dimethomorph gave positive responses when tested in Chinese hamster lung at high doses. Dimethomorph was weakly positive when tested in human lymphocytes when treated up to the highly toxic dose of 422 micrograms/milliliter, but was negative in the absence of activation at all doses. Dimethomorph was negative in the cell transformation assay in Syrian hamster embryo cells with and without activation at up to cytotoxic levels.
870.7485	Metabolism and pharmacokinetics	Oral administration of dimethomorph results in rapid excretion into the urine and feces of rats. For all treatment protocols, most (80–90%) of the radiolabel administered was excreted in the feces. A considerably smaller amount (6–16%) was excreted in the urine and only minimal levels (0.1–0.4%) were detected in the organs and tissues. Rapid absorption may be inferred by the rapid excretion of metabolites in the urine and bile. Retention of dimethomorph or ^{14}C-dimethomorph-derived radioactivity was generally ≤1% for most tissues although the liver exhibited slightly higher levels (1.4%). Urinary metabolites resulted from demethylation of the dimethoxyphenyl ring and oxidation of the morpholine ring. Biliary excretion exhibited first-order kinetics with a low-dose (10 mg/kg) half-life of approximately 3 hours and a high-dose (500 mg/kg) half-life of 11 hours for males and about 6 hours for females. Biliary metabolites accounted for most of the fecal excretion following low-dose treatment. The major biliary metabolites were glucuronides of one and possibly two of the compounds produced by demethylation of the dimethoxyphenyl ring.
870.7600	Dermal penetration	In a dermal penetration study, radio-labeled ^{14}C-dimethomorph in water was administered dermally to 4 male SD rats/group for 8 hours at doses of 7.73 (2.5% w/v aqueous suspension) or 79.62 mg/kg (25% w/v aqueous suspension). Dermal absorption was 0.05%, 0.07% and 0.27% of the administered dose from rats 4, 8, and 24 hours after dermal treatment at 7.73 mg/kg, and 0.02%, 0.16% and 0.12% of the dose at 79.62 mg/kg. Six days after treatment the percent total absorption of the dose in the 7.73 and 79.62 mg/kg was 4.76 and 1.20 percent respectively.

B. 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 level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

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 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. A summary of the toxicological endpoints for dimethomorph used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIMETHOMORPH 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	Not applicable.	Not applicable.	No effects attributable to a single exposure (dose) were observed from oral toxicity studies including developmental toxicity studies.
Chronic Dietaryall populations	NOAEL= 11 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.1 mg/kg/day	Rat carcinogenicity study LOAEL = 46.3 mg/kg/day based on decreased body weight and statistically significant increases in liver lesions in female rats.
Short-term Dermal (1 to 7 days)(Residential)	oral study NOAEL = 60 mg/kg/day (dermal absorption factor = 5%).	LOC for MOE = 100	Developmental Toxicity Study in the rat LOAEL = 160 mk/kg/day based on decreased body weight, decreased body weight gain, and decreased food consumption.
Intermediate -Term Dermal (1 week to several months)(Residential)	Oral study NOAEL = 15 mg/kg/day (dermal absorption factor = 5%	Not applicable.	Subchronic Feeding Study in Dogs LOAEL = 43 mg/kg/day based on decreased absolute and relative prostate weight and possible threshold liver effects.
Long-Term Dermal (several months to lifetime)	Not applicable.	Not applicable.	The use pattern does not indicate a concern for long-term exposure/risk.
Short-Term Inhalation (1 to 7 days)	Oral study NOAEL = 60 mg/kg/day (inhalation absorption factor = 100%)	LOC for MOE = 100	Developmental Toxicity Study in the Rat LOAEL = 160 mg/kg/day based on decreased body weight, decreased body weight gain, and decreased food consumption.
Intermediate-Term Inhalation (1 week to several months)	Oral study NOAEL = 15 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	Subchronic Feeding Study in Dogs LOAEL = 43 mg/kg/day based on decreased absolute and relative prostrate weight and possible threshold liver effects.
Long-Term Inhalation (several months to lifetime)	Not applicable.	Not applicable.	The use patterns do not indicate a concern for long-term exposure/risk.
Cancer (oral, dermal, inhalation)	Not applicable.	Not applicable.	Dimethomorph was classified as Not Likelyto be a human carcinogen. This classification is based on the lack of evidence of carcinogenicity in mice and rats when tested at doses that were judged to be adequate to assess carcinogenicity.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.493) for the residues of dimethomorph, in or on grape at 3.5 ppm; hops, cones, dried at 60 ppm; raisins at 6.0 ppm; potato at 0.05 ppm; potato, wet peel at 0.15 ppm; tomato at 0.5 ppm and tomato, paste at 1.0 ppm. There were no U.S. registrations for grape, hop, or raisins at the time the tolerances were established for these food commodities. Time-limited tolerances are established for residues of dimethomorph in or on cantaloupe, cucumber, squash, and watermelon at 1.0 ppm in connection with the use of the pesticide under section 18 emergency exemptions. Risk assessments were conducted by EPA to assess dietary exposures from dimethomorph 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. An acute exposure assessment was not performed since no effects attributable to a single exposure (dose) were observed from oral toxicity studies.

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 Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The chronic exposure assessment is based on very conservative assumptions that all commodities that have tolerances for dimethomorph and the commodities included in this action will contain residues (100 percent crop treated) at the tolerance level.

iii. *Cancer.* A cancer exposure assessment was not performed since dimethomorph is classified as Not Likely to be a human carcinogen.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for dimethomorph 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 dimethomorph.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would 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 dimethomorph they are further discussed in the aggregate risk sections in Unit III.E of this preamble.

Based on the FIRST and SCI-GROW models the EECs of dimethomorph for chronic exposures are estimated to be 28.5 ppb parts per billion (ppb) for surface water and 0.30 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dimethomorph 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*. Section 408(b)(2)(D)(v) 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.''

EPA does not have, at this time, available data to determine whether dimethomorph has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, dimethomorph does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that dimethomorph has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. 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 database 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. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity database for dimethomorph and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X. The FQPA factor was reduced because:

i. The toxicology database is complete; the developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

ii. A developmental neurotoxicity study is not required by the Agency. There is no evidence of neurotoxicity in the current toxicity database.

iii. The dietary (food and water) exposure assessment did not indicate a concern for potential risk to infants and children when tolerance level residues were used. The use of tolerance level residues results in an overestimate of dietary exposure.

iv. Residential exposure is not expected since dimethomorph is not registered for residential use.

E. 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 + residential 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 U.S. EPA 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 groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to

the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An appropriate endpoint attributable to a single exposure for the general U.S. population (including infants and children) was not identified. An acute risk assessment was not performed, since no acute risk from dietary exposure is expected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to dimethomorph from food will utilize 5% of the cPAD for the U.S. population, 6% of the cPAD for infants less than 1 year old and 10% of the cPAD for children 1 to 6 years old, the subpopulation at greatest exposure. There are no residential uses that result in chronic residential exposure to dimethomorph. In addition, there is potential for chronic dietary exposure to dimethomorph in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DIMETHOMORPH

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.10	5	28.5	0.30	3,300
Infants, less than 1 year old	0.10	6	28.5	0.30	940
Children, 1 to 6 years old	0.10	10	28.5	0.30	900
Females 13 to 50 years old	0.10	5	28.5	0.30	2,900

3. *Short- and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dimethomorph 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 do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. The Agency concludes that pesticidal uses of dimethomorph are not likely to pose a carcinogenic hazard to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate method is available for enforcement of the tolerances. FAMS 002–02 is a high pressure liquid chromatography analytical method with ultraviolet detection and is adequate for determining residues of dimethomorph per se. The method has been successfully validated by the Agency's Analytical Laboratory. The method may be requested from: Paul Golden, U.S. EPA/OPP/BEAD/ACB, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: 410–305–2960; FAX 410–305–3091; e-mail address: RAM Mailbox.

B. International Residue Limits

There are no established or proposed maximum residue limits or tolerances for dimethomorph in or on hop, dried cones; lettuce, leaf; lettuce, head; vegetable, cucurbit, group; or vegetable, bulb, group.

V. Conclusion

Therefore, the tolerance is established for residues of dimethomorph, [(E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine]], in or on hop, dried cones at 60 ppm; lettuce, leaf and lettuce, head at 10 ppm; vegetable, cucurbit, group at 0.5 ppm; and vegetable, bulb, group at 2.0 ppm.

VI. 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 ID number OPP–2002–0221 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 26, 2002.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 VI.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 docket ID number OPP–2002–0221, 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 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal

Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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: September 23, 2002.

Peter Caulkins,

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), 346(a) and 371.

2. Section 180.493 is amended by removing the entry for ''Hops, cones, dried [1]'', and by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.493 Dimethomorph; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * *	*
Hop, dried cones	60
* * * *	*
Lettuce, head	10
Lettuce, leaf	10
* * * *	*
Vegetable, bulb, group	2.0
Vegetable, cucurbit, group	0.5

* * * * *

[FR Doc. 02–24485 Filed 9–26–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0195; FRL–7199–5]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on fig at 0.10 part per million (ppm); herb, fresh, subgroup at 3.0 ppm; herb, dried, subgroup at 22 ppm; vegetable, root and tuber, group at 0.10 ppm; caneberry subgroup at 0.70 ppm; grape at 0.50 ppm; grape, raisin at 0.70 ppm; peanut at 0.02 ppm; and beet, sugar, molasses at 0.75 ppm. This regulation also increases established tolerances for cattle, meat to 0.50 ppm; cattle, meat byproducts to 2.0 ppm; cattle, fat to 6.5 ppm; milk to 2.5 ppm; and milk, fat to 27 ppm. The Interregional Research Project Number 4 (IR-4) and Elanco Animal Health, A Division of Eli Lily and Company, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0195, must be received on or before November 26, 2002.

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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0195 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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