The Administrator certifies that the approval of the redesignation request will not affect a substantial number of small entities.

E. Unfunded Mandates

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

F. Submission to Congress and the Comptroller General

Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

G. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 14, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such an action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).) EPA encourages interested parties to comment in response to the proposed redesignation rather than petition for judicial review, unless the objection arises after the comment period allowed for in the proposal.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Reporting and recordkeeping.

Dated: September 3, 1998.

Gail Ginsburg,

Acting Regional Administrator, Region 1.

40 CFR part 52, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C 7401 et seq.

Subpart Y—Minnesota

2. Section 52.1220 is amended by adding paragraph c(46) to read as follows:

§ 52.1220 Identification of plan.

* * * * *

(c) * * *

(46) On April 24, 1997, the State of Minnesota submitted Administrative Order amendments for sulfur dioxide for two Northern States Power facilities: Inver Hills and Riverside.

(i) Incorporation by reference.

(A) Amendment Two, dated and effective November 26, 1996, to administrative order approved in paragraph (c)(30) of this section for Northern States Power-Riverside Station.

(B) Amendment Three, dated and effective November 26, 1996, to administrative order and amendments approved in paragraphs (c)(35) and (c)(41), respectively, of this section for Northern States Power-Inver Hills Station.

[FR Doc. 98–26897 Filed 10–9–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300740; FRL–6036–7]

RIN 2070–AB78

Dimethomorph [(E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine]; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the fungicide dimethomorph [(*E,Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine] in or on potatoes. American Cyanamid Company requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective October 13, 1998. Objections and requests for hearings must be received by EPA on or before December 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300740], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300740], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300740]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Product Manager 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Room 265, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 26, 1997 (62 FR 14418)(FRL–5594–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 7F4816) for tolerance by American Cyanamid Company, Agricultural Products Division, P.O. Box 400, Princeton, NJ 08543–0400. This notice included a summary of the petition prepared by American Cyanamid Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.493 be amended by establishing a tolerance for residues of the fungicide dimethomorph [(*E,Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine], in or on potatoes at 0.05 parts per million (ppm).

I. Risk Assessment and Statutory Findings

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).

II. 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 dimethomorph and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of dimethomorph on potatoes at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by dimethomorph are discussed below.

1. *Acute toxicity.* Technical dimethomorph is relatively non-toxic when administered acutely to laboratory animals (Toxicity Category III for Rat Acute Oral, Acute Dermal, Acute Inhalation, Primary Eye Irritation (conjunctival irritation clearing in 4 days); Toxicity Category IV for Mice Acute Oral, *Z*-isomer Rat Acute Oral, *E*-isomer Rat Acute Oral, Acute Dermal, Primary Eye Irritation (grade I irritation clearing in 48 hours), Primary Skin Irritation (grade I irritation at abraded skin sites only, clearing by day 2); Dermal Sensitization - not a sensitizer).

2. *Subchronic toxicity*- i. *A 90-day feeding - rat.* Technical grade dimethomorph (98.7% a.i.) was administered in the diet to groups of 10 male and 10 female Charles River CD Sprague-Dawley rats at concentrations of 0, 40, 200, or 1,000 ppm (0, 2.9, 14.2, or 73 mg/kg/day for male rats, and 0, 3.2, 15.8, or 82 mg/kg/day for female rats, respectively) for 13 weeks, 4 days. A Lowest Observed Adverse Effect Level (LOAEL) was not established because the highest dose tested produced no biologically significant effects. The No Observed Adverse Effect Level (NOAEL) is >1,000 ppm (73 mg/kg/day for males, and 82 mg/kg/day for females).

ii. *A 90-day feeding-dog.* Dimethomorph (technical, 96.6% a.i.) was administered to four male and four female Beagle dogs/dose group in the diet at concentrations of 0, 150, 450, or 1,350 ppm (equivalent to doses of 0, 5, 15 or 43 mg/kg/day for males, and 0, 6, 15 or 44 mg/kg/day for females) for 13 weeks. Prostate fibrosis occurred in all four of the high-dose males but not in any other male. Clinical signs were limited to intermittent incidences of salivation, lip-licking, tremors, and subdued behavior; these signs were more prevalent in the 150 and 1,350 ppm groups but were not considered of toxicologic significance. The critical toxic effect appeared to be a significant decrease in the mean absolute and relative prostate weights of the high-dose (1,350 ppm) male dogs relative to untreated controls. Therefore, based upon 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), the LOAEL is 1,350 ppm (43 mg/kg/day). The NOAEL is 450 ppm (15 mg/kg/day).

3. *Chronic toxicity*— i. *In rats.* The LOAEL for systemic toxicity was 750 ppm (57.7 mg/kg/day) for female rats based on decreased body weight and significant increase in the incidence of ''ground glass'' foci in the liver and 2,000 ppm (99.9 mg/kg/day) for male rats based on decreased body weight and increased incidence of arteritis. The corresponding NOAEL's are 200 ppm (11.9 mg/kg/day) for females, and 750 ppm (36.2 mg/kg/day) for males.

ii. *In dogs.* At 1,350 ppm, ALK phosphatase activity was increased throughout the study in both sexes (245% males. 310% females). The LOAEL for systemic toxicity is 1,350 ppm, based on decreased prostate weight in males. The NOAEL was 450 ppm.

4. *Carcinogenicity*— i. *In rats.* 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. The LOAEL for systemic

toxicity was 2,000 ppm in males and 750 ppm in females. The NOAEL's were 750 ppm (33.9 mg/kg/day) for males and 200 ppm (11.3 mg/kg/day) for females.

ii. *In 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 (17% and 22% less than control in males and females, respectively, at 1,000 mg/kg/day). The NOAEL for systemic toxicity was 100 mg/kg/day.

5. *Developmental toxicity*— i. *In rats*. Maternal LOAEL = 160 mg/kg/day, 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; Maternal NOAEL = 60 mg/kg/day; Developmental LOAEL = 160 mg/kg/day based on increased resorptions; Developmental NOAEL = 60 mg/kg/day.

ii. *In rabbits*. Maternal LOAEL = 650 mg/kg/day, based on decreased body weights and body weight gain. Maternal NOAEL = 300 mg/kg/day. No developmental toxicity was observed in this study. Developmental NOAEL = 650 mg/kg/day.

6. *Two-generation reproduction study in rats*. Parental toxicity LOAEL = 1,000 ppm, based on decreased body weights and body weight gain; Parental NOAEL = 300 ppm (20.8 mg/kg/day for males; 24 mg/kg/day for females); Developmental Toxicity LOAEL = 1,000 ppm based on delayed incisor eruption at day 10 postpartum; Developmental Toxicity NOAEL = 300 ppm; Reproductive Toxicity NOAEL = 1,000 ppm (69 mg/kg/day for males; 79.3 mg/kg/day for females).

7. *Mutagenicity*. The studies indicate that 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 i.p. However, dimethomorph gave positive responses when tested in CH lung and in human lymphocytes. It was negative in the cell transformation assay in Syrian hamster embryo cells with and without activation at up to cytotoxic levels.

8. *Dermal penetration*. Radio-labeled ^{14}C-dimethomorph (97.6%; labeled in the chlorophenyl ring) was administered dermally to 4 male SD rats/group in water for 8 hours at doses of 7.73 (2.5% w/v aqueous suspension) or 79.62(25% w/v aqueous suspension)mg/kg. 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. Mean percent recovery of the ^{14}C for dose levels of 7.73 and 79.62 mg/kg was 104.1% and 92.1%, respectively.

9. *Neurotoxicity*. There are no acute, subchronic, or developmental neurotoxicity studies available in the data base for dimethomorph. However, in none of the subchronic, chronic, developmental, or reproduction studies was there any indication that the nervous system was affected by administration of dimethomorph. No evidence of neurotoxicity was observed in the available data base.

10. *General metabolism*. Rat Oral administration of dimethomorph (10 mg/kg single dose; 10 mg/kg 14-day repeated dose; 10 mg/kg 7-day repeated dose; 500 mg/kg single dose) 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. Saturation of absorption following single high doses (500 mg/kg) was indicated by large amounts (≈50%) of radioactivity in the feces being associated with parent compound. For low- or high-dose treatment, urinary excretion in female rats tended to be greater (up to 2-fold in low-dose rats) than that of male rats. Retention of dimethomorph or ^{14}C-dimethomorph-derived radioactivity was generally ≤ 1% for most tissues although the liver exhibited slightly higher levels (1.4%) and higher levels in the gastrointestinal tract organswas due to radioactivity in the lumenal contents. 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. The report provided a proposed metabolic pathway for dimethomorph.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA did not select a dose and endpoint for an acute dietary risk assessment due to the lack of toxicological effects attributable to a single exposure (dose) in either the rat or the rabbit developmental toxicity studies. Therefore an acute RfD was not calculated.

2. *Short- and intermediate-term toxicity*. EPA established NOAELs of 60 mg/kg/day and 15 mg/kg/day to be used in risk assessments for workers for short- and intermediate-term dermal and inhalation exposures, respectively. The NOAEL for short-term exposure is based on the maternal NOAEL established in the rat developmental toxicity study and the NOAEL for intermediate-term exposure is based on the NOAEL established in the 90-day dog feeding study. As the exposures are by dermal and inhalation routes and these are oral studies, a dermal absorption factor of 5 percent, derived from the dermal absorption study, is included in the risk assessment. Inhalation absorption is assumed to be 100%.

3. *Chronic toxicity*. EPA selected a NOAEL of 11 mg/kg/day established in the chronic oncogenicity feeding study in the rat. This NOAEL was nearly identical to that established in the rat chronic feeding study. The LOAEL was 46.3 mg/kg/day based on decreased body weight and liver lesions in female rats. A 100 fold safety factor was applied (10 for inter-species extrapolation, and 10 for intra-species variation). Thus, the chronic RfD was calculated to be 0.1 mg/kg/day. The EPA FQPA Safety Factor Committee determined that, for chronic dietary risk assessment, the 10x factor to account for enhanced sensitivity to infants and children (as required by FQPA) should be removed. Neither a chronic dermal nor inhalation endpoint were identified as the current use pattern does not indicate a concern for long term exposure.

4. *Carcinogenicity*. There was no increased incidence of neoplasms in the rat chronic or carcinogenicity studies or in the mouse carcinogenicity study. EPA determined that the chemical had been tested at adequate dosage in the rat study, as demonstrated by the high incidence of arteritis in males, and the pronounced decrease in body weight in females at the mid- and high-dose levels. EPA also determined that the high dose tested (1,000 mg/kg/day) in the mouse study was the maximum dose required by the test guidelines for a dietary oncogenicity study. Therefore,

EPA classified dimethomorph as ''not likely'' to be a human carcinogen.

C. Exposures and Risks

1. *From food and feed uses.* Time-limited tolerances are established for residues of dimethomorph in or on cantaloupes, cucumbers, tomatoes, squash and watermelons at 1.0 ppm, potatoes at 0.05 ppm, tomato paste at 6.0 ppm and tomato puree at 2.0 ppm in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Risk assessments were conducted by EPA to assess dietary exposures from dimethomorph as follows:

i. *Acute exposure and risk.* 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 dietary exposure assessment is not required because no acute toxicological effects endpoints were identified for dimethomorph due to the lack of toxicological effects attributable to a single exposure (dose) in either the rat or the rabbit developmental toxicity studies.

ii. *Chronic exposure and risk.* EPA's Dietary Exposure Evaluation Model (DEEM89) was used for conducting a chronic dietary (food only) exposure analysis (risk assessment). The analysis evaluates individual food consumption, as reported by respondents in the USDA 1989-1992 Nationwide Food Consumption Survey, and accumulates exposure to the chemical for each commodity. In conducting this chronic dietary (food) risk assessment, EPA made very conservative assumptions: that all commodities having dimethomorph tolerances will contain residues of dimethomorph and those residues will be at the level of the tolerance. These assumptions result in an overestimate of human dietary exposure. All section 18 tolerances (cantaloupes, watermelons, cucumbers, squash, tomatoes) are included in this dietary risk assessment.

Using the assumptions and data parameters described above, the DEEM89 exposure analysis results in a theoretical maximum residue contribution (TMRC) (exposure) that is equivalent to the following percentages of the chronic RfD:

Population Subgroup	TMRC $_{food}$ (mg/kg/day)	Percent RfD
U.S. Population (48 states)	0.0018	1.8
Nursing Infants (<1 year old)	0.00054	0.5
Non-Nursing Infants (<1 year old)	0.0021	2.1
Children (1-6 years old)	0.0039	3.9
Children (7-12 years old)	0.0027	2.7
Females (13-19 yrs/not preg. or nursing)	0.0020	2.0
Males (13-19 years)	0.0019	1.9
U.S. Population - Summer Season	0.0021	2.1
Northeast Region	0.0021	2.1
Hispanics	0.0020	2.0
Non-Hispanic other than black or white	0.0021	2.1

EPA does not consider the chronic dietary risk to exceed the Agency's level of concern.

2. *From drinking water.* There is no established Maximum Contaminant Level for dimethomorph in drinking water. No health advisory levels have been established for residues of dimethomorph in drinking water. The predicted dimethomorph surface and ground water concentrations are well below EPA's drinking water level of concern (DWLOC). EPA used the SCI-GROW (Screening Concentration In Ground Water) Model to estimate the Estimated Environmental Concentration (EEC) of dimethomorph residues in ground water. The reported EEC for dimethomorph residues using SCI-GROW is 0.26 ppb. EPA used GENEEC (Generic Estimated Environmental Concentration) Model to estimate acute and chronic EECs of dimethomorph residues in surface water. The GENEEC model estimated that, with the present use pattern, surface water concentrations of dimethomorph ranged from a peak of 28 ppb to a 56 day concentration of 24 ppb. EPA's level of concern for chronic exposure to residues of dimethomorph range from 960 ppb for children 1-6 years old to 3,400 ppb for the U.S. population and males 13 years and older. Therefore, exposure from water is below EPA's level of concern for all of the populations examined.

i. *Acute exposure and risk.* Because no acute dietary endpoint was determined, an acute water and dietary exposure risk assessment is not required.

ii. *Chronic exposure and risk.* EPA conducts the drinking water risk assessment by using the worst case scenario of EEC found from either ground or surface water. The EEC reported for dimethomorph residues in ground water using SCI-GROW is 0.26 ppb. This is much less than the surface water EECs (24.4 ppb for 56-days) generated using GENEEC. Therefore, only the surface water EECs were used in conducting the aggregate dietary (food + water) risk assessment. Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic drinking water levels of concern (DWLOC) for drinking water were calculated. To calculate the chronic DWLOC, the chronic dietary food exposure (from DEEM analysis) was subtracted from the chronic RfD. DWLOCs were then calculated using the default body weights and drinking water consumption figures. EPA's surface drinking water levels of concern from chronic exposure to dimethomorph using modeling data are 3,400 ppb for the U.S. Population and males 13 years and older, 2,900 ppb for females 13 years and older, and 960 ppb for children (1-6 years of age). These levels are all greater than the GENEEC concentration level (24.4 ppm for 56-days). Therefore, EPA does not expect exposure to dimethomorph in drinking water to be above our level of concern.

3. *From non-dietary exposure.* There are no registered or proposed residential uses for dimethomorph. Therefore, residential or inhalation exposures were not evaluated in the risk assessment. A risk assessment was evaluated for occupational risk to workers who could be exposed to dimethomorph through simultaneous dermal and inhalation exposure. Agricultural workers evaluated in this analysis include: ground mixer/loaders, ground applicators, aerial mixer/loaders and aerial applicators. The dermal and inhalation short-term margin of exposure (MOE) ranged from 1,200 for aerial mixer/loaders using the wettable

powder (WP) to 190,000 for aerial applicators. The intermediate-term MOEs range from 290 for aerial mixer/loaders using WP to 47,000 for aerial applicators. Exposure from post-application of dimethomorph resulted in MOEs ranging from 23,000 for short-term to 5,800 for intermediate-term. None of these MOEs exceed HED's level of concern (i.e., acceptable MOE > 100) for occupationally exposed workers. Therefore, these workers are unlikely to experience adverse health effects under the conditions evaluated.

4. *Cumulative exposure to substances with 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. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. An acute aggregate risk assessment is not required because no acute dietary endpoint was determined.

2. *Chronic risk*. EPA concludes that the chronic exposure to dimethomorph from food will utilize 1.8% of the RfD for the U.S. population, 2.0% for females (13+ not pregnant or nursing), 1.9% for males 13 years and older, and 3.9% for children ages 1 through 6 years of age. The surface drinking water levels of concern from chronic exposure to dimethomorph using modeling data are 3,400 ppb for the U.S. Population and males 13 years and older, 2,900 ppb for females 13 years and older and 960 ppb for children (1-6 years of age). These levels are all greater than the GENEEC chronic concentration level (24.4 ppb for 56 days) and the SCI-GROW ground water level of 0.26 ppb. There are no registered residential uses of dimethomorph. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to dimethomorph in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, EPA concludes that there is reasonable certainty that no harm will result to either adults or children from chronic aggregate exposure to dimethomorph residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Although short- and intermediate-term endpoints were identified, there are no residential uses for dimethomorph. Therefore, an aggregate risk assessment is not required for short- and intermediate-term endpoints.

4. *Aggregate cancer risk for U.S. population*. Dimethomorph was classified as ''not likely'' to be a human carcinogen). Therefore, a carcinogenic aggregate risk assessment is not required.

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

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of dimethomorph, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. The toxicology data on dimethomorph provides no indication of enhanced sensitivity of infants and children based on the results from developmental studies conducted with rats and rabbits as well as a two-generation reproduction study conducted with rats. In neither the rat developmental toxicity study nor in the 2-generation study were any toxic effects observed at doses lower than in the parents. No developmental toxicity was demonstrated in the rabbit developmental toxicity study.

FFDCA of 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 pre-and post-natal toxicity and the completeness of the database 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. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Pre- and post-natal sensitivity*. The data provided no evidence of special sensitivity of rats or rabbits to in utero and/or postnatal exposure to dimethomorph. In the prenatal developmental study in rats, an increased incidence of post implantation loss, considered by EPA to be minimal, was observed in the presence of maternal toxicity. In the developmental toxicity in rabbits, no evidence of developmental toxicity was seen, even at the highest dose tested. In the two-generation study in rats, effects in the offspring were observed only at dose levels that produced parental toxicity. There is no evidence that dimethomorph is a neurotoxic chemical. EPA determined that the 10x factor to account for enhanced sensitivity of infants and children be removed.

iii. *Conclusion*. There is a complete toxicity database for dimethomorph and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. An acute aggregate risk assessment is not required because no acute dietary endpoints were identified for dimethomorph.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to dimethomorph from food will utilize 4% of the RfD for infants and children.

EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to dimethomorph in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* Although short- and intermediate-term endpoints were identified, there are no residential uses for dimethomorph. Therefore, an aggregate risk assessment is not required for short- and intermediate-term endpoints.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and in animals are adequately understood. The major residue of regulatory concern is the parent dimethomorph compound. Tolerances on animal commodities are not required in conjunction with this use. There is no need for additional poultry metabolism data at this time since no uses are pending on poultry feed items.

B. Analytical Enforcement Methodology

An adequate method is available for enforcement of the proposed tolerances. Method FAMS 002-04 (High Performance Liquid Chromatography (HPLC), Ultraviolet (UV) detection) is adequate for determining residues of dimethomorph per se in/on potatoes. A confirmatory method is also available (FAM 022-03).

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

EPA has concluded that residue data submitted in support of the tolerance for imported potatoes indicate that a tolerance level of 0.05 ppm is an adequate level for domestic potatoes. In addition, domestic field trial data supported the tolerance level of 0.05 ppm on potatoes and indicated that dimethomorph residues do not pose an adverse health risk to humans under the use conditions. Therefore, EPA has no objection to the establishment of a tolerance of 0.05 ppm for residues of the fungicide dimethomorph in/on potatoes under 40 CFR 180.493.

D. International Residue Limits

There are no Canadian, Mexican, or Codex MRLs established for dimethomorph for the commodities associated with this request: consequently, a discussion of international harmonization is not relevant.

E. Rotational Crop Restrictions

EPA concluded it is permissible to rotate to leafy vegetables and root crops after a 120-day plant back interval. Rotation to potatoes will be permitted at any time. For crops other than potatoes, leafy vegetables, and root crops, a 1-year plant back interval will be required.

IV. 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 potatoes at 0.05 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 14, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300740] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are

received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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). 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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 the rule in the **Federal Register**. This 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 30, 1998.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In section 180.493, by revising paragraph (a) to read as follows:

§ 180.493 Dimethomorph [(E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine]; tolerances for residues.

(a) *General.* A tolerance is established for the 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 commodity:

Commodity	Parts per million
Potatoes	0.05

* * * * *

[FR Doc. 98–27396 Filed 10–9–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300720; FRL–6030–3]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolite containing (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on dates, hops, and strawberries. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on dates and strawberries in California, and on hops in Idaho, Oregon and Washington. This regulation establishes a maximum permissible level for residues of hexythiazox in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and be revoked on September 15, 2000.

DATES: This regulation is effective October 13, 1998. Objections and requests for hearings must be received by EPA on or before December 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300720], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300720], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300720]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the insecticide hexythiazox in or on hops at 2.0 ppm, dates at 0.1 ppm, strawberries at 3.0 parts per million (ppm). These tolerances will expire and be revoked on September 15, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

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

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Hexythiazox on Dates, Hops, and Strawberries and FFDCA Tolerances

The state of California has petitioned EPA to allow the emergency use of hexythiazox on both strawberries and