

**§ 1100.1 Cross-references to employee ethical conduct standards, financial disclosure and financial interests regulations and other conduct rules.**

Employees of the United States Section of the International Boundary and Water Commission are subject to the executive branch standards of ethical conduct contained in 5 CFR part 2635, the executive branch financial disclosure regulations contained in 5 CFR part 2634, and the executive branch financial interests regulations contained in 5 CFR part 2640, as well as the executive branch employee responsibilities and conduct regulations contained in 5 CFR part 735.

Dated: April 26, 2006.

**Tony R. Chavez,**

*Designated Agency Ethics Official, United States Section of the Internal Boundary and Water Commission.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0216; FRL-7770-8]

**Dimethenamid-p; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of dimethenamid-p in or on squash, winter. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on squash, winter. This regulation establishes a maximum permissible level for residues of squash, winter. The tolerance will expire and is revoked on June 30, 2009.

**DATES:** This regulation is effective May 3, 2006. Objections and requests for hearings must be received on or before July 3, 2006.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2006-0216. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) web site. EDOCKET, EPA's electronic public docket and comment system was

replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov>. Follow the on-line instructions. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

• **Important Note:** OPP will be moving to a new location the first week of May 2006. As a result, from Friday, April 28 to Friday, May 5, 2006, the OPP Regulatory Public Docket will NOT be accepting any deliveries at the Crystal Mall #2 address and this facility will be closed to the public. Beginning on May 8, 2006, the OPP Regulatory Public Docket will reopen at 8:30 a.m. and deliveries will be accepted in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. The mail code for the mailing address will change to (7502P), but will otherwise remain the same. The OPP Regulatory Public Docket telephone number and hours of operation will remain the same after the move.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

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

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

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

**II. Background and Statutory Findings**

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a time-limited tolerance for residues of the herbicide dimethenamid-p, 1-(RS)-2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthien-3-yl)-acetamide in or on squash, winter at 0.01 parts per million (ppm). Dimethenamid-p is a 90:10, S:R mixture of dimethenamid isomers, and is already included in the existing tolerances codified at 40 CFR 180.464. This tolerance will expire and is revoked on June 30, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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

from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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

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 the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### III. Emergency Exemption for Dimethenamid-p on Squash, Winter and FFDCA Tolerances

Amiben (chlorambem) was the primary herbicide used in squash and other cucurbits until 1991, when production of this herbicide ceased. EPA did not revoke tolerances until 1999 to allow use of remaining stocks. Growers began applying Amiben in banded strips over the crop row, as the product was no longer available. By 2000, weed control had become a major difficulty in squash.

Winter squash grown in western Oregon is processed for both puree and seeds. Confectionary seed production constitutes 70% to 90% of the market, depending on the year. Seed yield has been dropping precipitously during the last 5 years (2000–2004). Fruit yield for puree has not changed dramatically, but is far short of the production goals expected before amiben was removed from the market. Growers typically expected 25 to 30 tons per acre, and in some cases yields were as high as 35 tons per acre during the 1980's. In contrast, fruit/puree yield during the 5–

year period of 2000–2004 averaged only about 18 tons per acre. The production cost have risen over the last 5 years, while the price paid per product has remained nearly constant.

Consequently, growers had cut back their acreage of winter squash during 2000–2004 to well below 4,500 acres, solely due to the lack of weed control and resulting yield/economic losses.

EPA has authorized under FIFRA section 18 the use of dimethenamid-p on squash, winter for control of nightshade and other summer weeds in Oregon. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of dimethenamid-p in or on squash, winter. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this tolerance will expire and is revoked on June 30, 2009, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on squash, winter after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicates that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether dimethenamid-p meets EPA's registration requirements for use on squash, winter or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of dimethenamid-p by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Oregon to use this pesticide on this crop under

section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for dimethenamid-p, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

### IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of dimethenamid-p and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a time-limited tolerance for residues of dimethenamid-p in or on squash, winter at 0.01 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

#### A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. A 3X UF was added for short-term dermal and inhalation exposure for *S*-dimethenamid-p due to the absence of a maternal NOAEL, and a lower LOAEL in comparison to *S*-dimethenamid-*RS* shown in the developmental toxicity study in rats.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) 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 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 SF.

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

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q\* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10<sup>-6</sup> 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 margin of exposure (MOE)<sub>cancer</sub> = point of departure/exposures) is calculated.

Much of the existing toxicological and residue chemistry data base for dimethenamid is based on studies conducted with the racemic (50:50) mixture of *S* and *R* isomers. EPA has previously concluded that the data base is adequate for the risk assessment of both the racemic dimethenamid and the 90:10, *S*:*R* dimethenamid-p in the **Federal Register** of September 24, 2004 (69 FR 57197) (FRL-7680-1). A summary of the toxicological endpoints for dimethenamid-p used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIMETHENAMID-P FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario*	Dose Used in Risk Assessment, Interspecies, Intraspecies, and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–49 years of age) based on <i>RS</i> data	NOAEL = 75 milligram/kilogram/day (mg/kg/day) UF = 100 Acute RfD = 0.75 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.75 mg/kg/day	Developmental toxicity in rabbits Maternal LOAEL = 150 mg/kg/day based on abortions and decreased body weight gain and food consumption Developmental LOAEL = 150 mg/kg/day based on post-implantation loss
Acute dietary (general population including infants and children)	Not applicable. No studies identify an acute hazard (dose and endpoint) based on a single-oral exposure (dose)		
Chronic dietary (all populations) based on <i>RS</i> data	NOAEL = 5 mg/kg/day UF = 100 Chronic RfD = 0.05 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.05 mg/kg/day	Chronic/carcinogenicity rats LOAEL = Male/Female (M/F); 36/49 mg/kg/day based on decreased body weight and body weight gain in both sexes, increased food conversion ratios in females, and increased microscopic hepatic lesions in both sexes
Dermal absorption based on <i>RS</i> data	30%	No studies are available. Value estimated from the ratio of the LOAEL for maternal weight decrement in developmental study to LOAEL for male weight decrement in the 21-day dermal study. Ratio of (developmental rabbit maternal LOAEL, body weight) / (21-day dermal rabbit LOAEL for systemic toxicity, body weight) x 100 = (150/500) x 100 = 30%	
Dermal short-term (1–30 days)	NOAEL = 25/3(UF) = 8 mg/kg/day Dermal absorption = 30% UF = 3 <sup>2</sup> ; MOE = 300 <sup>5</sup>	Developmental toxicity study in rats (MRID 44332243). LOAEL = 25 mg/kg/day was based on maternal body weight decrement, body weight gain decrement and decreased food consumption.	
Dermal Intermediate-term, (1–6 months)	NOAEL = 6.8 mg/kg/day (F) Dermal absorption = 30% UF = 1 MOE = 100	Chronic feeding study in rats (MRID 41706808 and 42030102). LOAEL = 36/49 mg/kg/day (M/F) based on decreased body weight and body weight gain and at termination increased microscopic hepatic lesions. NOAEL = 5.1/6.8 mg/kg/day for (M/F)	
Inhalation, short-term (1–30 days)	NOAEL = 8 mg/kg/day (F) Inhalation absorption = 100% UF = 3 <sup>2</sup> MOE = 300	Same as dermal, short-term	

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIMETHENAMID-P FOR USE IN HUMAN RISK ASSESSMENT—CONTINUED

Exposure/Scenario*	Dose Used in Risk Assessment, Interspecies, Intraspecies, and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Inhalation intermediate-term (1–6 months)	NOAEL = 6.8 mg/kg/day (F) Inhalation absorption = 100% UF = 1 MOE = 100		Same as dermal intermediate-term
Cancer	Classified as “C” a possible human carcinogen; however, no Q1* was has been established for an assessment of cancer risk.		

\* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to FQPA.

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.464(a)) for the residues of dimethenamid-p, in or on bean, dry, seed; beet, garden, roots; beet, garden, tops; beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops; corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, forage; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernal plus cob with husk removed; corn, sweet, stover; garlic; horseradish; onion, dry bulb; peanut, hay; peanut, nutmeat; shallot, bulb; sorghum, grain; sorghum, grain, forage; sorghum, grain, stover; soybean, seed; and tuberous and corm vegetables. The tolerance expression includes both the R and S isomers, these tolerances also cover the registered uses of dimethenamid-p. The current tolerances for all plant commodities are set at 0.01 ppm. Risk assessments were conducted by EPA to assess dietary exposures from dimethenamid-p 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 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996, and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute dietary analysis is conservative, based on tolerance-level residues and 100% crop treated assumptions for all commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as

reported by respondents in the USDA 1994, 1996, and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary analysis is conservative, based on tolerance-level residues and 100% crop treated assumptions for all commodities.

iii. *Cancer.* Dimethenamid-p has been classified as a Category “C” (possible human carcinogen). Based on increased tumor incidence only in rats (not mice). The Agency determined that a quantitative cancer risk assessment is not required. The RfD approach was used to estimate cancer risk. Therefore, the chronic (non-cancer) risk assessment is an adequate estimate of cancer risk as well as other chronic effects.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier I model) before using PRZM/EXAMS (a Tier II model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS

incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

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

Based on the PRZM/EXAMS and SCI-GROW models, the estimated environmental concentrations (EECs) of dimethenamid-p for acute exposures are estimated to be 49 parts per billion (ppb) for surface water and 0.42 ppb for ground water. The EECs for chronic exposures are estimated to be 7.9 ppb for surface water and 0.42 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). Dimethenamid-p is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDC A 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.”

Unlike other pesticides for which EPA has followed a cumulative risk approach

based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to dimethenamid-p and any other substances and dimethenamid-p 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 dimethenamid-p 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at <http://www.epa.gov/pesticides/cumulative/>.

#### C. Safety Factor for Infants and Children

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

2. *Developmental toxicity studies.* In a developmental toxicity study in rats, maternal toxicity was evidenced by excessive salivation, increased liver weight and reduced body weight gain and food consumption at 215 and 425 milligrams per kilogram per day (mg/kg/day). Developmental toxicity was evidenced by an increased incidence of resorption in the 425 mg/kg/day rats. The maternal NOAEL is 50 mg/kg/day and the maternal LOAEL is 215 mg/kg/day. The developmental NOAEL is 215 mg/kg/day and the developmental LOAEL is 425 mg/kg/day.

In a developmental toxicity study in rabbits, maternal toxicity was evidenced

by decreased body weight, food consumption and increased abortion/premature delivery at 75 and 150 mg/kg/day. Developmental toxicity was evidenced by increased abortion/premature delivery and hyoid alae angulated changes in the 150 mg/kg group. The maternal NOAEL is 37.5 mg/kg/day and the maternal LOAEL is 75 mg/kg/day. The developmental NOAEL is 75 mg/kg/day and the developmental LOAEL is 150 mg/kg/day.

3. *Reproductive toxicity study.* In a 2-generation reproductive study in rats, parental toxicity was evidenced by significant reductions in body weight and food consumption in males and significant increases in absolute and relative liver weights in both sexes. Significant reductions in pup weight during lactation occurred at 150 mg/kg/day. The parental NOAEL is 36 mg/kg/day and the parental LOAEL is 150 mg/kg/day. The reproduction NOAEL is 36 mg/kg/day and the reproduction LOAEL is 150 mg/kg/day.

4. *Prenatal and postnatal sensitivity.* No offspring prenatal or postnatal susceptibility to either *RS*-dimethenamid or *S*-dimethenamid-p was seen in a rabbit or two rat developmental studies and reproduction study. There is low concern for prenatal or postnatal toxicity since the developmental effects from the *S* and *RS* mixture are similar and occur at similar doses.

5. *Conclusion.* There is a complete toxicity data base for dimethenamid-p and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined the 10X safety factor to protect infants and children should be reduced to 1X because there are low concerns, and no residual uncertainties with regard to prenatal and/or postnatal toxicity. Additionally, developmental, reproductive, and prenatal-postnatal effects were seen only at levels above those that caused effects in adults.

#### D. Aggregate Risks and Determination of Safety

Aggregate dietary risk for dimethenamid-p is assessed by comparing acute and chronic dietary (food and drinking water) exposure estimates to their respective aPAD and cPAD, with risk expressed as a percent

of the PAD. Acute and chronic water residues were incorporated into the dietary exposure analyses. There are no residential uses of dimethenamid-p. Therefore, the reported acute and chronic dietary exposures are aggregate food and water risks associated with the proposed section 18 use (squash, winter), and the existing registered uses.

The acute and chronic aggregate (food and drinking water) exposure assessment was conducted using the DEEM software with the Food Commodity Intake Database (DEEM™/FCID), Version 1.3) which incorporates consumption data from the USDA CSFII, 1994–1996 and 1998. The 1994–1996 and 1998 data are based on the reported consumption of more than 20,000 individuals over 2 non-consecutive survey days. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption “events” for acute exposure assessment. Exposure estimates are expressed in mg/kg body weight/day and risk as a percent of the aPAD/cPAD.

An upper-bound (Tier 1) acute and chronic aggregate risk assessment was conducted for dimethenamid-p food commodities and drinking water combined. The residue estimate for each food commodity is based on the tolerance for that crop (0.01 ppm) and each crop is assessed as if 100% of the crop has been treated with dimethenamid-p. The EEC inputs (acute/chronic) for drinking water are described as “Tier 2,” but are considered upper-bound estimates for finished drinking water. It should also be noted that, like the tolerance level inputs for foods, the residue inputs for drinking water are point estimates rather than a residue distribution (as seen in probabilistic assessments).

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure to dimethenamid-p from food will occupy 0.32% of the aPAD for females 13–49 years and older. EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DIMETHENAMID-P

Population Subgroup	PAD, mg/kg/day	DEEM™-FCID	
		Exposure, mg/kg/day	%PAD
Acute dietary estimates (95 <sup>th</sup> percentile of exposure)			
Females 13–49 years	0.75	0.002416	<1

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to dimethenamid-p from food will utilize 0.4% of the cPAD for

the U.S. population, 1.2% of the cPAD for all infants <1 year old and 0.7% of the cPAD for children 1–2 years old. There are no residential uses for dimethenamid-p that result in chronic

residential exposure to dimethenamid-p. 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 DIMETHENAMID-P

Population Subgroups	PAD, mg/kg/day	DEEM™-FCID	
		Exposure, mg/kg/day	%PAD
Chronic PAD Dietary Estimates			
U.S. Population	0.05	0.000205	<1
All infants (<1 year)	0.05	0.000605	1.2
Children (1–2 years)	0.05	0.000329	<1
Children (3–5 years)	0.05	0.000315	<1
Children (6–12 years)	0.05	0.000221	<1
Youth (13–19 years)	0.05	0.000163	<1
Adults (20–49 years)	0.05	0.000187	<1
Adults (50+ years)	0.05	0.000189	<1

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Dimethenamid-p is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

#### 4. *Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Dimethenamid-p is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* Dimethenamid-p has been classified as a Category “C” (possible human carcinogen). Based on increased tumor incidence only in rats (not mice), the Agency determined that a quantitative cancer risk assessment is

not required. The RfD approach was used to estimate cancer risk. Therefore the chronic (non-cancer) risk assessment is an adequate estimate of cancer risk as well as other chronic effects.

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

#### V. Other Considerations

##### A. *Analytical Enforcement Methodology*

An adequate enforcement method is available for determining dimethenamid residues in plants and soil. The Gas Chromatography/Nitrogen Phosphorus Detection (GC/NPD) method (AM-0884-0193-1) has been validated by the Agency and submitted for publication in FDA’s Pesticide Analytical Manual, Volume II. The method does not separate the *R* and *S* isomers of dimethenamid and the limit of quantitation (LOQ) is 0.01 ppm. Thus, adequate enforcement methodology is available to enforce the tolerance

expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. *International Residue Limits*

There are no CODEX or Canadian maximum residue limits established for dimethenamid or dimethenamid-p. Therefore, tolerance harmonization is not germane to the current section 18 proposed use.

#### VI. Conclusion

Therefore, the time-limited tolerance is established for residues of dimethenamid-p, 1-*RS*-2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethylthien-3-yl)-acetamide in or on squash, winter at 0.01 ppm.

#### VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 EPA-HQ-OPP-2006-0216 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 July 3, 2006.

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 issue(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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14<sup>th</sup> St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone

number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number EPA-HQ-OPP-2006-0216, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**.

#### 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

### VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of FFDCA. 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 FIFRA section 18 exemption under section 408 of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 section 408(n)(4) of FFDCA. 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.

**IX. Congressional Review Act**

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: April 25, 2006.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.464 is amended by adding text to paragraph (b) after the paragraph heading to read as follows:

**§ 180.464 Dimethenamid; tolerances for residues.**

\* \* \* \* \*

(b) \* \* \* A time-limited tolerance is established for residues of dimethenamid-p, 1-(*RS*)-2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethylthien-3-yl)-acetamide in or on the following commodity:

Commodity	Parts per million	Expiration/revocation date
Squash, winter .....	0.01	06/30/09

\* \* \* \* \*

[FR Doc. 06-4161 Filed 5-2-06; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0301; FRL-8060-3]

**Glufosinate Ammonium; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for indirect or inadvertent residues of glufosinate ammonium and its metabolite in or on raw agricultural commodities. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). **DATES:** This regulation is effective May 3, 2006. Objections and requests for hearings must be received on or before July 3, 2006.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-

OPP-2005-0301. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. (EDOCKET, EPA’s electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

• **Important Note:** OPP will be moving to a new location the first week of May 2006. As a result, from Friday, April 28 to Friday, May 5, 2006, the OPP Regulatory Public Docket will NOT be accepting any deliveries at the Crystal Mall #2 address and this facility will be closed to the public. Beginning on May 8, 2006, the OPP Regulatory

Public Docket will reopen at 8:30 a.m. and deliveries will be accepted in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. The mail code for the mailing address will change to (7502P), but will otherwise remain the same. The OPP Regulatory Public Docket telephone number and hours of operation will remain the same after the move.

**FOR FURTHER INFORMATION CONTACT:** Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: [miller.joanne@epamail.epa.gov](mailto:miller.joanne@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.