ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

OPP–300863; FRL–6081–5

RIN 2070–AB78

Difenoconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the fungicide difenoconazole (((2*S*,4*R*)/(2*R*,4*S*)/(2*R*,4*R*)/(2*S*,4*S*)) 1–(2–(4–(4-chlorophenoxy)-2-chlorophenyl)-4-methyl-1,3-dioxolan-2-yl)methyl-1*H*–1,2,4-triazole) in or on the raw agricultural commodities bananas at 0.2 parts per million (ppm); wheat forage at 0.1 ppm; wheat grain at 0.1 ppm; wheat straw at 0.1 ppm; eggs at 0.05 ppm; milk at 0.01 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 2, 1999. Objections and requests for hearings must be received by EPA on or before August 2, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300863], 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–300863], 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 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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–300863]. 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: Cynthia Giles-Parker, 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: Rm. 249, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–7740, giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 25, 1997 (62 FR 40075) (FRL–5726–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170) announcing the filing of a pesticide petition (PP 5E4526) to establish an import tolerance on bananas by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing. In the **Federal Register** of December 2, 1998 (63 FR 66535) (FRL–6043–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA of 1996 (Pub. L. 104–170) announcing the filing of a pesticide petition (PP 2F4107) to establish a tolerance on wheat and related animal commodities by Novartis Crop Protection, Inc. that included a summary of the petition prepared by the same company. There were also no comments received in response to this second notice of filing.

The petitions requested that 40 CFR 180.475 be amended by establishing tolerances for the fungicide, difenoconazole, in or on the raw agricultural commodities bananas at 0.2 ppm; wheat forage at 0.1 ppm; wheat grain at 0.1 ppm; wheat straw at 0.1 ppm; eggs at 0.05 ppm; milk at 0.01 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm.

I. Background 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 difenoconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances in/on the raw agricultural commodities wheat forage at 0.1 ppm; wheat grain at 0.1 ppm; wheat straw at 0.1 ppm; eggs at 0.05 ppm; milk at 0.01 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm, and an import tolerance for the fungicide difenoconazole in or on the raw agricultural commodity bananas at 0.2 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 difenoconazole are discussed in this unit.

B. Toxicological Endpoints

1. *Acute toxicity*. Difenoconazole possesses low acute toxicity by the oral, dermal and inhalation routes of exposure. It is considered to be a mild eye and slight skin irritant and is not a dermal sensitizer. The acute oral LD_{50} in rats is 1,453 milligrams per kilogram (mg/kg). The acute dermal LD_{50} is estimated to be greater than 2,010 mg/kg. The acute inhalation LC_{50} in rats is greater than 3,300 mg/m^3. The primary eye irritation category is III and the primary skin irritation category is IV.

2. *Short- and intermediate-term toxicity.* Subchronic studies of the effects of difenoconazole in mice and rats manifested decreased body weights, decreased body weight gains, and effects on the liver at 200 ppm and higher. Microscopic examination of the eyes of dogs at 3,000 ppm revealed unilateral and bilateral lenticular cataracts in both sexes of animals. In a 13–week feeding study in mice, nearly all mice fed 7,500 or 15,000 ppm died during the first week of the study; there was a significantly decreased body weight gain, hepatocellular enlargement and vacuolation in animals receiving 2,500 ppm difenoconazole in the diet; and hepatocyte enlargement in animals receiving 200 ppm. The lowest observable adverse effect level (LOAEL) was considered to be 200 ppm based on decreased body weight gains and liver histopathology and the no observable adverse effect level (NOAEL) was 20 ppm (equivalent to 2.0 mg/kg in males and 4.4 mg/kg in females). In a 13–week feeding study in rats, the LOAEL was 200 ppm (10 mg/kg/day) in females, based on a decrease in body weights (concurrent with a negative trend for food consumption), and 750 ppm (37.5 mg/kg/day) for males, based on increases in absolute liver weights; the NOAEL was 20 ppm (equivalent to 1 mg/kg/day). A 21–day dermal toxicity study using rabbits produced a LOAEL of 100 mg/kg/day based on statistically significant decrements in body weight, body weight gain, and food consumption, and a NOAEL of 10 mg/kg/day. A feeding study in dogs for 26 weeks produced a LOAEL of 3,000 ppm based on unilateral or bilateral cataracts in all three female and one of three male dogs. The NOAEL was concluded to be 1,000 ppm (31.3 to 34.0 mg/kg/day).

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for difenoconazole at 0.01 mg/kg/day. This RfD is based on the NOAEL of 0.96 mg/kg/day (20 ppm) for males in a 104–week chronic toxicity/carcinogenicity study in rats and using an uncertainty factor of 100 (10x for interspecies extrapolation and 10x for intraspecies variability. The NOAEL for females (at the 20 ppm dietary exposure) was 1.27 mg/kg/day. The LOAEL in this study was 500 ppm (24.12 mg/kg/day for males and 32.79 mg/kg/day for females), based on cumulative decreases in body weight gains and hepatocellular hypertrophy. In the dog, the LOAEL was 500 ppm, based on decreased body weight gains (and decreased food intake) and the NOAEL was 100 ppm (3.4 to 3.7 mg/kg/day) in a 52–week chronic dietary toxicity study.

The results of the 2–generation reproductive and developmental toxicity studies do not demonstrate increased sensitivity of infants and children to difenoconazole. In a developmental toxicity study in rats, the maternal NOAEL was determined to be 20 mg/kg/day and the maternal LOAEL was 100 mg/kg/day based on decreased body weight gains and decreased food consumption. In the same study, the developmental NOAEL was 100 mg/kg/day and the developmental LOAEL was 200 mg/kg/day based on the incidence of bifid or unilateral ossification of the thoracic vertebrae, which was significantly increased on a fetal basis, and significant increases in the average number of ossified hyoid and decreases in the number of sternal centers of ossification (per fetus per litter). The average number of ribs was also significantly increased with accompanying increases in the number of thoracic vertebrae and decreases in the number of lumbar vertebrae in this group. In a developmental toxicity study in rabbits, the LOAEL is 75 mg/kg/day for maternal toxicity based on decreases in body weight gain and food consumption, and the NOAEL is 25 mg/kg/day for maternal toxicity; for developmental toxicity, the LOAEL is 75 mg/kg/day based on increases in post-implantation loss and resorptions per doe, and decreases in fetal body weight, and the NOAEL is 25 mg/kg/day. In a 2–generation reproduction study in rats, for parental toxicity, the LOAEL of 250 ppm (12.5 mg/kg/day) is based on the decrease in maternal body weight gain and the NOAEL is 25 ppm (1.25 mg/kg/day; for reproductive toxicity the LOAEL of 250 ppm (12.5 mg/kg/day) is based on decreased pup weights at day 21 and the NOAEL is 25 ppm (1.25 mg/kg/day).

Neurotoxicity studies are not applicable because difenoconazole is not a cholinesterase inhibitor and there is no evidence in the available data base that difenoconazole possesses neurotoxic properties. It is not structurally related to known neurotoxic compounds.

Difenoconazole was not mutagenic with or without metabolic activation in two microbial/mammalian microsome plate incorporation assays. In an *in vivo* micronucleus assay, no increases in micronucleated polychromatic erythrocyte counts were seen in the bone marrow cells of mice given difenoconazole. This chemical was negative in an *in vitro* unscheduled DNA synthesis (UDS) assay with primary rat hepatocytes.

4. *Carcinogenicity*. Chronic feeding studies in mice showed decreased body weight gains in male and female mice at termination. Treatment related non-neoplastic lesions were confined to the liver and were supported by the clinical chemistry data at a level of 300 ppm (46.29 and 57.79 mg/kg/day for males and females, respectively). Liver tumors were observed in mice at 300 ppm and higher; however, based on the excessive toxicity observed at the two highest doses of 2,500 and 4,500 ppm (females terminated after 2 weeks due to excessive toxicity resulting in moribundity and death), the absence of tumors at the two lower doses of 10 and 30 ppm, and the absence of genotoxic effects, in 1994 the Agency determined that the appropriate cancer classification for difenoconazole is C (possible human carcinogen) and advocated the use of the margin of exposure (MOE) approach to determining exposure/risk. However, at this time the Agency has not defined the level of concern for cancer using the MOE approach. Therefore, a quantitative risk analysis was conducted using the Q_1* approach. The Q_1* was determined to be 1.57×10^{-1} $(mg/kg/day)^{-1}$. This value incorporates the 3/4 scaling factor and is based on the male mouse liver adenomas and/or carcinomas combined.

Metabolism studies in rats indicated that peak absorption occurred between 24 and 48 hours post-dosing. Elimination in the feces ranged between 78 and 94% and in the urine between 8 and 21%. Difenoconazole did not accumulate to any appreciable extent since tissues contained less than 1.0%

of the radioactivity after 7 days post-exposure. From the proposed metabolic pathway of difenoconazole in rats, the compound undergoes successive oxidation and conjugation reactions. One of the metabolites, CGA–205375, accounts for 6–24% of the applied dose and is found only in the urine and feces of high dose (300 mg/kg) rats. The presence of this intermediate in the excreta of only high dose rats suggests that its rate of further biotransformation has reached saturation at the high dose. Additionally, excretion of radioactivity in the bile, feces, and urine of rats orally dosed with ^{14}C-difenoconazole is consistent with saturation of the gastrointestinal absorption of the chemical at 300 mg/kg. The distribution, metabolism, and excretion of difenoconazole are not sex-dependent.

C. Exposures and Risks

1. *From food and feed uses.* Time-limited tolerances previously existed in (40 CFR 180.475) for the residues of difenoconazole in or on the following raw agricultural commodities: eggs at 0.05 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; milk at 0.01 ppm; wheat forage at 0.1 ppm; wheat grain at 0.1 ppm; and wheat straw at 0.1 ppm. The time limits were conditional on submission by the company of several studies. However, even though Novartis Crop Protection, Inc. submitted the studies before the expiration date of these tolerances, the tolerances expired on December 31, 1998, because the Agency was unable to complete review of the studies by that date. These tolerances are reestablished and made permanent by this rule. In addition to the above tolerances, import tolerances also exist for the residues of difenoconazole on barley grain at 0.1 ppm; eggs at 0.05 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; milk at 0.01 ppm; rye grain at 0.1 ppm; and wheat grain at 0.1 ppm. These import tolerances are unaffected by this rule. Risk assessments were conducted by EPA to assess food exposures from difenoconazole as follows:

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance. Anticipated residue data used in the current dietary risk analysis were calculated from field trial data. The anticipated residues used were 0.01 for bananas; 0.000019 for eggs; 0.0000043 for egg whites; 0.000046 ppm for egg yolk; 0.000041 ppm for fat of cattle, goats, hogs, horses, and sheep; 0.00012 ppm for kidney of cattle, goats, hogs, horses, and sheep; 0.000014 ppm for meat of cattle, goats, hogs, horses, and sheep; 0.00044 ppm for meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep; 0.000013 ppm for milk; 0.01 ppm for plantains; 0.0000030 ppm for poultry fat; 0.000034 ppm for poultry kidney; 0.000006 ppm for poultry meat; 0.000023 ppm for poultry meat byproducts (except kidney); 0.005 ppm for sweet corn; and 0.005 ppm for wheat grain.

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

The Agency used PCT information as follows: 3% crop treated for sweet corn, 9% crop treated for wheat, and 10.5% imported for barley. The percent imported data are used in the same way PCT data are used. This refinement is used because difenoconazole is not registered for use in the United States. The percentage means that 10.5% of the barley used (potentially or actually) for human consumption in the United States is imported; it is even more conservative because it also assumes that all such imported barley has difenoconazole residues.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates is supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which difenoconazole may be applied in a particular area.

i. *Acute exposure and risk.* Acute 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. An acute risk assessment is required for difenoconazole. The acute NOAEL of 25 mg/kg/day is based on the developmental toxicity study in rabbits, in which the endpoint effects at the LOAELs were post-implantation loss and resorptions per doe and a significant decrease in fetal weight at 75 mg/kg/day during days 7 and 19. The uncertainty factor used was 100, resulting in an acute RfD of 0.25 mg/kg/day. The Agency's detailed acute analysis estimated the distribution of single-day exposures for females older than 13 years. A dose and endpoint were not selected for the general U.S. population and infants and children because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats or rabbits that are attributable to a single exposure. The

Dietary Exposure Evaluation Model (DEEM) analysis evaluated the data in the USDA 1989–91 Continuing Surveys for Food Intake by Individuals (CSFII). The acute analysis used tolerance level residues and 100% crop treated. The FQPA Safety Factor was reduced to 1x. Therefore, the acute Population Adjusted Dose (PAD) and the acute RfD are the same. For acute risk the Agency's level of concern is for estimated exposure greater than 100% of the RfD. Total exposures from the proposed new and preexisting food and feed uses of difenoconazole, at the 95th percentile of exposure are: (a) Females (13+/pregnant/not nursing), 0.000913 mg/kg/day (<1% of the RfD); (b) females (13+/nursing), 0.001079 mg/kg/day (<1% of the RfD); (c) females (13–19 years/not pregnant or nursing), 0.000941 mg/kg/day (<1% of the RfD); (d) females (20+ years/not pregnant or nursing), 0.000804 mg/kg/day (<1% of the RfD); and (e) females (13–50 years), 0.000869 mg/kg/day (<1% of the RfD). The acute risk from food exposure does not exceed the Agency's level of concern.

ii. *Chronic exposure and risk.* A chronic risk assessment was required for difenoconazole. The RfD used for the chronic analysis is 0.01 mg/kg based on the NOAEL of 0.96 mg/kg/day for male rats in the 104–week combined chronic and carcinogenicity study in rats, in which the effects at the LOAEL were reduced body weight gains and hepatocellular hypertrophy. The chronic Dietary Exposure Evaluation Model (DEEM) exposure analysis used mean consumption (3–day average). Anticipated residues and PCT or percent imported data were used for selected commodities. The DEEM analysis evaluated the individual food consumption as reported by respondents in the 1989–91 CSFII and accumulated exposure to the chemical for each commodity. The FQPA Safety Factor was reduced to 1x. Therefore, the chronic PAD and the RfD are the same. The Agency's level of concern for chronic risk is exceeded if the exposure utilizes more than 100% of the RfD. Food exposures for the U.S. population and the most highly exposed subgroups are: (a) U.S. Population (48 states), 0.000005 mg/kg/day; (b) non-Hispanic (other than black or white), 0.000006 mg/kg/day; (c) all infants (<1 year old), 0.000016 mg/kg/day; (d) nursing infants (<1 year old), 0.000007 mg/kg/day; (e) non-nursing infants (<1 year old), 0.000019 mg/kg/day; (f) children (1–6 years old), 0.000011 mg/kg/day; (g) children (7–12 years old), 0.000005 mg/kg/day; (h) females (13+/nursing), 0.000006 mg/kg/day; and (i) seniors (55+), 0.000006 mg/kg/day. The subgroups presented are all children subgroups and the food exposures for the subgroups whose food exposures are higher than that of the U.S. population. The chronic risk from residues in food does not exceed the Agency's level of concern.

iii. *Cancer exposure and risk.* The Agency previously classified difenoconazole as a possible human carcinogen. This chemical would now be classified as a likely human carcinogen in accordance with the Agency's ''Proposed Guidelines for Carcinogenic Risk Assessment'' (April 10, 1996). Initially a non-linear, MOE approach was used for human risk characterization and extrapolation of risk using the 78–week mouse carcinogenicity study, in which the LOAEL effects related to tumor development (non-neoplastic hepatic lesions) were hepatocellular hypertrophy, necrosis, fatty changes, and bile stasis. Using the NOAEL of 4.7 mg/kg/day, the cancer MOE was determined to be 8,400 for the U.S. population. However, at this time the Agency has not defined the acceptable level of concern for cancer risk using the MOE approach. Therefore, the linear Q_1* approach was used for calculating cancer risk. A Q_1* of 0.157 $(mg/kg/day)^{-1}$ was determined, based on the male mouse liver adenoma and/or carcinoma combined tumor rates in the 78–week carcinogenicity study in mice. The exposure analysis estimating potential cancer risks for difenoconazole was performed using anticipated residues and PCT or percent imported refinements for selected commodities to determine Estimated Lifetime Cancer Risk for the general population. The DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 nationwide CSFII and accumulated exposure to the chemical for each commodity. The DEEM analysis used mean consumption values and assumes a 70–year lifetime exposure. The exposure calculated for the U.S. population (48 states) was 0.000005 mg/kg/day, providing a lifetime cancer risk estimate of 8.4×10^{-7} from residues in food. The cancer risk does not exceed the Agency's level of concern.

2. *From drinking water.* A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary, depending on the toxic endpoint, with drinking water consumption and body weights. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water but they do have an indirect regulatory impact through aggregate exposure and risk assessments.

In calculating DWLOCs, the default assumptions for drinking water consumption are 2 liters consumed per day by adults and 1 liter consumed per day by children. The default assumptions for body weights are 70 kg for adult males, 60 kg for adult females, and 10 kg for children. Difenoconazole is used solely as a fungicidal seed treatment and is not expected to pose a major threat to ground and surface waters.

i. *Acute exposure and risk.* Model-derived estimates of the maximum concentrations of difenoconazole for acute exposure in ground and surface water are 0.125 parts per billion (ppb) and 0.00084 ppb, respectively, generated by the Screening Concentration in Ground Water (SCI-GROW) and Generic Expected Environmental Concentration (GENEEC) models, respectively. The SCI-GROW and GENEEC model estimated maximum concentrations were compared directly to the DWLOC for acute exposure. The Agency has calculated the DWLOC for acute exposure to difenoconazole in surface and ground water for females (13+ years old, nursing) to be 7,500 ppb. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute food exposure (from the DEEM analysis) was subtracted from the acute RfD to obtain the acceptable acute exposure to difenoconazole in drinking water. The DWLOC was then calculated using the default body weights and drinking water consumption figures. The maximum estimated concentrations of difenoconazole in surface water are less than the Agency's DWLOCs for difenoconazole in drinking water as a contribution to acute aggregate exposure.

ii. *Chronic exposure and risk.* The SCI-GROW model was used to estimate a maximum concentration of difenoconazole in ground water of 0.00084 ppb and the GENEEC model concentration was divided by three and used to estimate an average concentration of difenoconazole in surface water of 0.016 ppb. For chronic

(non-cancer) exposure to difenoconazole in surface and ground water, the DWLOCs are 350 ppb for the U.S. population, 300 ppb for the subgroup females (13+ years old/nursing), and 100 ppb for the subgroup non-nursing infants (<1 year old). To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic food exposure (from the DEEM analysis) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to difenoconazole in drinking water. The maximum estimated concentration of difenoconazole in surface water is less than the Agency's DWLOCs for difenoconazole in drinking water as a contribution to chronic (non-cancer) exposure.

iii. *Cancer exposure and risk*. Estimates generated by models of the maximum concentration of difenoconazole for chronic exposure in ground water is 0.00084 ppb (from the SCI-GROW model) and for the estimated average concentration in surface water is 0.016 ppb (from the GENEEC model). For chronic (cancer) exposure to difenoconazole in surface and ground water, the DWLOC is 0.048 ppb for the U.S. population. To calculate the DWLOC for chronic exposures relative to a carcinogenic toxicity endpoint, the chronic (cancer) food exposure (from the DEEM analysis) was subtracted from the ratio of the negligible cancer risk to the Q_1* to obtain the acceptable chronic (cancer) exposure to difenoconazole in drinking water. DWLOCs were then calculated using the default drinking water consumptions and body weights. The average estimated concentration of difenoconazole in surface water is less than the Agency's DWLOC for difenoconazole in drinking water as a contribution to cancer aggregate exposure.

3. *From non-dietary exposure*. Difenoconazole is not currently registered for use on residential non-food sites.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Difenoconazole is a member of the triazole class of pesticides. Other members of this class include cyproconazole, fenbuconazole, propiconazole, tebuconazole, and uniconazole. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' While the Agency has some information in its files that may be helpful in determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodology to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will enable it to develop and apply policies for evaluating the cumulative effects of chemicals having a common mechanism of toxicity. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments. There are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism will be assumed).

EPA does not have, at this time, available data to determine whether difenoconazole 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, difenoconazole 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 difenoconazole has a comon 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

There are no proposed or existing residential uses for difenoconazole and occupational uses of difenoconazole will not result in post-application residential exposure. Therefore, aggregate exposure risk assessment has been limited to food and water only, using the exposure estimates and risk characterizations described above.

1. *Acute risk*. From the acute food risk assessment, a high-end exposure estimate was calculated for the subgroup females 13+ years old. In this subgroup less than 1% of the RfD is occupied by food exposure. The acute food exposure for females 13+ years old is below the Agency's level of concern. An acute RfD is not established for the general population including infants and children because there were no effects observed in oral toxicity studies including maternal toxicity in the developmental toxicity studies in rats and rabbits attributable to a single exposure. The maximum estimated concentrations of difenoconazole in surface and ground water are less than the Agency's DWLOCs for difenoconazole as a contribution to acute aggregate exposure. Therefore, the Agency concludes with reasonable certainty that residues of difenoconazole in drinking water do not contribute significantly to the aggregate acute human health risk at the present time, considering the present uses and the uses proposed in this action. EPA bases this determination on a comparison of estimated concentrations of difenoconazole in surface waters and ground waters to DWLOCs for difenoconazole. The estimated concentrations of difenoconazole in surface and ground waters are derived from water quality models that use conservative assumptions regarding pesticide transport from the point of application to surface and ground water. Because the Agency considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOC may vary as those uses change. If new uses are added in the future, the Agency will reassess the potential impacts of difenoconazole on drinking water as a part of the aggregate acute risk assessment process.

2. *Chronic risk*. Chronic risk estimates associated with exposure to difenoconazole in food and water do not exceed the Agency's level of concern. The chronic DEEM food exposure analysis used mean consumption (3–day average). Anticipated residues and PCT data for select commodities were used to determine food exposure for the general population and 28 subgroups. The Agency has concluded that the percentage of the RfD that will be utilized by chronic food exposure to residues of difenoconazole is less than 1% of the RfD for all groups and subgroups. The estimated average concentrations of difenoconazole in surface and ground water are less than the Agency's DWLOCs for

difenoconazole as a contribution to chronic dietary aggregate exposure. Therefore, the Agency concludes with reasonable certainty that residues of difenoconazole in drinking water do not contribute significantly to the aggregate chronic human health risk at the present time considering the present uses and the uses proposed in this action. The Agency bases this determination on a comparison of estimated concentrations of difenoconazole in surface and ground waters to DWLOCs for difenoconazole. The estimates of difenoconazole in surface and ground waters are derived from water quality models that use conservative assumptions regarding pesticide transport from the point of application to surface and ground water. Because the Agency considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOCs may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of difenoconazole on drinking water as a part of the aggregate chronic risk assessment process.

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.

Since no registered residential uses or exposure scenarios were identified for short- and intermediate-term exposure scenarios, short- and intermediate-term aggregate risks are deemed to be negligible.

4. *Aggregate cancer risk for U.S. population*. The DEEM cancer food exposure analysis used anticipated residues and PCT information to estimate the lifetime cancer risk for the general population. The food exposure was calculated to be 0.000005 mg/kg/day and the lifetime dietary risk was 8.4 x 10^{-7}, since there are no uses resulting in post-application exposure. The aggregate exposure for cancer includes only food and water. Cancer risk estimates associated with exposure to difenoconazole from food and water do not exceed the Agency's level of concern.

The estimated average concentrations of difenoconazole in surface and ground water are less than the Agency's DWLOCs for difenoconazole as a contribution to cancer aggregate exposure. Therefore, the Agency concludes with reasonable certainty that residues of difenoconazole in drinking water do not contribute significantly to the aggregate chronic human health risk at the present time considering the present use and uses proposed in this action. The Agency bases this determination on a comparison of estimated concentrations of difenoconazole in surface and ground waters to DWLOCs for difenoconazole. The estimates of difenoconazole in surface and ground waters are derived from water quality models that use conservative assumptions regarding pesticide transport from the point of application to surface and ground water. Because the Agency considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOCs may vary as those uses change. If new uses are added in the future, the Agency will reassess the potential impacts of difenoconazole on drinking water as a part of the aggregate cancer risk assessment process.

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 difenoconazole 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 difenoconazole, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–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.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base 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. 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 postnatal sensitivity*. The data provided no indication of increased susceptibility of rats or rabbits to in utero or postnatal exposure to difenoconazole.

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

The FQPA 10x additional safety factor for infants and children was reduced to 1x because: (a) The toxicology data base is complete, (b) there is no indication of increased susceptibility of rat or rabbit fetuses during in utero and/or postnatal exposure in the developmental and reproductive toxicity data, (c) in the absence of complete environmental fate data for difenoconazole and for protection of infants and children, worst-case fate parameters will be used in the models for ground and surface source drinking water exposure assessments resulting in estimates that are upper-bound concentrations, and (d) there are currently no registered residential uses for difenoconazole and therefore, non-dietary exposure to infants and children is not expected.

2. *Acute risk*. An acute RfD is not established for the general population including infants and children because there were no effects observed in oral toxicity studies including maternal toxicity in the developmental toxicity studies in rats and rabbits attributable to a single exposure. The Agency concludes that acute risks to infants and children are negligible.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to difenoconazole from food will utilize less than 1% 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. The estimated average concentrations of difenoconazole in surface and ground water are less than the Agency's DWLOC for chronic exposure among nursing infants (<1 year old) to difenoconazole. Despite the potential for exposure to difenoconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. Since no registered residential uses or exposure scenarios were identified for

short- and intermediate-term exposure scenarios among the general population, short- and intermediate-term aggregate risk are negligible.

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 difenoconazole residues.

III. Other Considerations

A. Nature of the Residue In Plants and Animals

The nature of the residue in wheat is understood as a result of acceptable metabolism studies being performed in wheat RACs. The major terminal residues in wheat grain were the metabolites triazole and triazole acetic acid, and in wheat straw and forage were triazole alanine, triazole acetic acid, and CGA–205375. Parent difenoconazole was not detected in the grain and comprised <8% of the total recoverable residue (TRR) in forage and <0.4% of the TRR in straw. The nature of the residue is also understood in tomatoes, potatoes, and grapes, with the major terminal residues consisting of parent compound and triazole alanine in tomatoes, triazole alanine and conjugation with a number of naturally occurring substrates in potatoes, and metabolism of parent by hydroxylation of the phenyl ring and/or oxidative cleavage of the dioxolane ring, followed by cleavage of the carbon-carbon bridge between the phenyl and triazole rings. Similar results were observed in the wheat, tomato, and potato metabolism studies. Since the nature of the residue is understood in different crops, no metabolism studies for bananas were required. The Agency concluded that none of the difenoconazole metabolites warrant inclusion in the tolerance regulation or separate regulation or inclusion in the dietary risk assessment or additional metabolism or toxicological studies. The triazole metabolites (triazole, triazole alanine, triazole acetic acid) have previously been determined not to be of toxicological concern. CGA–205375 was determined not to be of concern due to the low potential for residues associated with seed treatment. This conclusion can be expanded to include triazole propanoic acid. Only the parent compound difenoconazole will be used in the tolerance expression.

The nature of the residue in animals is considered understood, for the purposes of the proposed uses, because the triazole metabolites have previously been determined not to be of toxicological concern and because CGA–205375 was determined not to be of concern due to the low potential for residues associated with seed treatment. The additional animal metabolite triazole propanoic acid was also determined not to be of concern because of the low residue potential associated with seed treatment.

B. Analytical Enforcement Methodology

The registrant proposed Method AG–575B as the analytical enforcement method for banana and wheat. Detection is then achieved by gas chromatography (GC) with a nitrogen/phosphorous detector. A confirmatory method, AG–657, differing from the enforcement method in the GC column and detector used, achieved good results in bananas fortified with difenoconazole. The Agency concludes that method AG–575B is adequate for enforcement purposes. The Agency has validated this method.

The registrant proposed method AG–544A as the analytical enforcement method for dairy and poultry tissue, eggs, and milk. The Agency concludes that method AG–544A is adequate for enforcement purposes. The Agency has validated this method.

Adequate enforcement methodology (e.g., gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

1. *Wheat*. For wheat, 15 field trials were conducted in 13 states. The wheat field trials were conducted at two application rates, 10.9 grams active ingredient (a.i.) per 100 lb. seed (1x) and 21.8 grams a.i. per 100 lb. seed (2x). The residue levels of difenoconazole in wheat grain (<0.01 ppm) and in wheat hay and straw (0.05 ppm) were less than the limit of quantitation (LOQ). The LOQ for wheat grain is 0.01 ppm and 0.05 ppm in wheat straw, hay, and forage. Wheat forage had levels ranging from <0.05 ppm to 0.077 ppm. The submitted data indicate that residues of difenoconazole will not exceed the tolerance for wheat RACs. The Agency has previously reviewed a processing study for spring wheat which was seed-treated (2x) and also foliar treated (10x) 28 days before harvest. No residues (<0.01 ppm) were detected in grain or any processed fraction.

2. *Bananas*. Nine field trials were conducted in Columbia, Honduras, and Ecuador. Field trials in each country were conducted at the single maximum application rate 0.22 lb. a.i. per hectare. Difenoconazole was applied 8 times for a total maximum application rate of 1.76 lb. a.i. per hectare. At each site whole banana fruit were collected zero days after the last application from the unbagged racemes (bunches). The residue levels of difenoconazole in whole bananas ranged from <0.02 to 0.13 ppm. The residue levels in banana pulp were all less than the LOQ (0.02 ppm). The residue levels in banana peel ranged from <0.02 to 0.25 ppm. An additional six field trials had been submitted and reviewed previously. These field trials were conducted in Costa Rica, Ecuador, Mexico, Guatemala, and Belize. Residue levels in these six field trials ranged from 0.03 to 0.16 ppm in whole unbagged bananas and <0.02 to 0.03 ppm in unbagged banana pulp. The submitted data indicate that residues of difenoconazole will not exceed the proposed tolerance level of 0.2 ppm for bananas. There are no processed commodities associated with bananas and therefore no tolerances for processed commodities are required.

3. *Meat, milk, poultry, and eggs*. The registrant requested a waiver for animal feeding studies based on the low potential for residues in feed items and the exaggerated rates used in the animal feeding studies. For now, the Agency is willing to accept the registrant's proposal to allow the animal metabolism studies to also serve as feeding studies. Feeding studies in cattle and poultry, as appropriate, will be needed for any future tolerance requested on potential livestock feed commodities which could lead to higher residues of concern in meat, milk, and eggs.

D. International Residue Limits

There are pending Codex Maximum Residue Levels for this compound in Mexico for oats, wheat, and barley.

E. Rotational Crop Restrictions

The nature of the residue is understood. The data indicate that the phenyl/triazole bridge of difenoconazole is cleaved in the soil and that triazole-specific metabolites are preferentially taken up by the rotational crops. The maximum TRR observed with phenyl-labeled difenoconazole was 0.009 ppm (wheat stalks) and with triazole-labeled difenoconazole was 0.314 ppm in wheat grain. The registrant has submitted the results of two confined crop rotation studies using phenyl-labeled difenoconazole. In the raw agricultural commodities of all rotational crops

planted 30–33 days after application of difenoconazole, the TRR was <0.01 ppm. These results support the proposed 30 –day plantback restrictions for all rotational crops.

IV. Conclusion

Therefore, tolerances are established for the fungicide difenoconazole (((2*S*,4*R*)/(2*R*,4*S*)/(2*R*,4*R*)/(2*S*,4*S*) 1–(2–(4–(4-chlorophenoxy)-2-chlorophenyl)-4-methyl-1,3-dioxolan-2-yl)methyl-1*H*–1,2,4-triazole) in or on the raw agricultural commodities bananas at 0.2 ppm; eggs at 0.05 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 ppm; milk at 0.01 ppm; wheat forage at 0.1 ppm; wheat grain at 0.1 ppm; and wheat straw at 0.1 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 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 August 2, 1999, 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 under the ''ADDRESSES'' section (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 regulation. 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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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 regulation under docket control number OPP–300863 (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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

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

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official 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 section 408(d) of the FFDCA 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 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 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 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 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: May 25, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

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

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

2. Section 180.475 is revised to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide difenoconazole (((2*S*,4*R*)/(2*R*,4*S*)/(2*R*,4*R*)/(2*S*,4*S*)) (1–((2–(2-chloro-4–(4-chlorophenoxy)phenyl)-4-methyl-1,3-dioxolan-2-yl)methyl)-1*H*–1,2,4-triazole) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat by-products	0.05
Eggs	0.05
Goats, fat	0.05
Goats, meat	0.05
Goats, meat by-products	0.05
Hogs, fat	0.05
Hogs, meat	0.05
Hogs, meat by-products	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, meat by-products	0.05
Milk	0.01
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat by-products	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat by-products	0.05
Wheat, forage	0.1
Wheat, grain	0.1
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.*

Commodity	Parts per million
Bananas[1]	0.2

[1]There are no U.S. registrations.

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 99–13947 Filed 6–1–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300807; FRL 6064–5]

RIN 2070–AB78

Iprodione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of iprodione, 3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, its isomer, 3-(1-methylethyl)-*N*-(3,5-