19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 14, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 3, 2000.

John Wise,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(263)(i)(D)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(263) * * *

(i) * * *

(D) * * *

(*2*) Rule 4.14 adopted on November 3, 1998.

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[FR Doc. 00–23651 Filed 9–14–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301005; FRL–6589–3]

RIN 2070–AB

Difenoconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of 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 canola, seed. 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 September 15, 2000. Objections and requests for hearings, identified by docket control number OPP–301005, must be received by EPA on or before November 14, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301005 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and

certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301005. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 5, 1999 (64 FR 24153) (FRL–6072–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Novartis Crop Protection, Inc. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to this notice of filing.

The petition requested that 40 CFR 180.475 be amended by establishing a tolerance 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 canola, seed at 0.01 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of 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 canola, seed at 0.01 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.

Difenoconazole possesses low acute toxicity. Technical difenoconazole had the following acute toxicology endpoints and toxicity categories. The acute oral toxicity Lethal Dose 50% (LD_{50}) was 1,453 milligrams per kilogram (mg/kg) (Toxicity Category III). The acute dermal toxicity LD_{50} was >2,010 mg/kg (Toxicity Category III). The acute inhalation Lethal Concentration 50% (LC_{50}) was >3,300 milligrams per cubic meter (mg/m^3; 4 hours of exposure; Toxicity Category IV). The primary eye irritation results were mild eye irritation, reversible in 7 days (Toxicity Category III). The primary skin irritation results were slight irritation (Toxicity Category IV). The dermal sensitization results were negative.

Subchronic studies 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. Decreased body weights, body weight gains, and food consumption were reported in a 21-day rabbit dermal study at the lowest observed adverse effect level (LOAEL) of 100 mg/kg/day.

Chronic studies in rats revealed decreased body weight gains and increased liver weights along with hepatocellular hypertrophy. Clinical chemistry data supported the liver pathology data suggesting that the liver was the primary target organ. There were no treatment-related neoplastic effects. The LOAEL was 500 ppm (equal to 24.12 and 32.79 milligrams per kilogram per day (mg/kg/day) for males and females, respectively) and the no observed adverse effect level (NOAEL) was 20 ppm (equal to 0.96 and 1.27 mg/kg/day for males and females, respectively).

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, the Cancer Peer Review Committee (CPRC) recommended for a cancer classification of C (possible human carcinogen) and advocated a Margin of Exposure (MOE) approach to risk assessment utilizing the NOAEL of 30 ppm (4.7 and 5.6 mg/kg/day in males and females, respectively) and the LOAEL of 300 ppm (46.3 and 57.8 mg/

kg/day in males and females, respectively) from the mouse study, using only those biological endpoints which were related to tumor development (i.e., hepatocellular hypertrophy, liver necrosis, fatty changes in the liver, and bile stasis).

The chronic study in beagle dogs revealed decreased body weight gains throughout the study at 500 ppm and increased levels of alkaline phosphatase at 1,500 ppm (equal to 51.2 and 44.3 mg/kg/day for males and females, respectively). The LOAEL was 500 ppm (equal to 16.4 and 19.4 mg/kg/day for males and females respectively) and the NOAEL was 100 ppm (equal to 3.4 and 3.7 mg/kg/day for males and females, respectively).

The results of the 2-generation and developmental studies did not demonstrate increased sensitivity to infants and children.

Neurotoxicity studies are not applicable as this chemical 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.

Mutagenicity studies indicated that difenoconazole was not mutagenic under the test conditions.

Metabolism studies in rats indicated that peak absorption occurred between 28 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-dosing. Difenoconazole undergoes successive oxidation and conjugation reactions. There is saturation of the metabolic pathway at high doses. The distribution, metabolism, and excretion of difenoconazole are not sex-dependent.

The overall quality of the toxicology data base is good. Confidence in the hazard and dose response assessment is also good. There are no toxicology data gaps.

B. Toxicological Endpoints

An inhalation dose/endpoint was not identified by the Agency because there is minimal concern for potential inhalation exposure/risk based on the low acute toxicity (Toxicity Category IV), application rate, application method, and number of applications (one time).

1. *Acute toxicity*. An acute Reference Dose (RfD) for difenoconazole of 0.25 mg/kg was established for the subpopulation group females 13+ years old, based on a NOAEL of 25 mg/kg from a developmental toxicity study in the rabbit. Effects at the next higher dose level of 75 mg/kg (the LOAEL) were based on post-implantation loss and resorptions per dose and a significant decrease in fetal body weight. These effects are presumed to occur after a single exposure *in utero* and therefore are considered to be appropriate for this risk assessment. The 10x FQPA Safety Factor, to provide increased protection for infants and children where this is needed, was reduced to 1x because there is no evidence that infants and children have an increased sensitivity to difenoconazole. As a result, the acute RfD and the acute Population Adjusted Dose (aPAD) are the same: 0.25 mg/kg. An acute dose and endpoint were not selected for the general population group (including infants and children) because there were no effects oberved in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose).

2. *Short- and intermediate-term toxicity*. For difenoconazole, the short-term dermal dose/endpoint was chosen from a developmental rabbit study. An oral NOAEL of 25 mg/kg/day was selected, based on post-implantation loss, increased resorptions per dose, and decreased body weight seen at 75 mg/kg/day (LOAEL). An intermediate-term dermal endpoint was chosen from a rat 2-generation reproduction study. The Agency chose an oral NOAEL of 1.25 mg/kg/day based on decreased pup weight on day 21 at 12.5 mg/kg/day (LOAEL).

3.*Chronic toxicity (non-cancer)*. EPA established an oral chronic RfD for difenoconazole at 0.01 mg/kg/day. This RfD is based on a 2-year chronic feeding/oncogenicity study in the rat, where the NOAEL of 0.96 mg/kg/day (statistically equal to 1.0 mg/kg/day) was based on cumulative decreases in body weight gains at the LOAEL of 24.12 mg/kg/day (500 ppm). This RfD was originally established by the Agency in 1994, and reconfirmed by the Agency in 1998. The chronic Population Adjusted Dose (cPAD) and the chronic RfD are the same because the FQPA Safety Factor has been reduced to 1x for difenoconazole. A long-term dermal endpoint was not identified by the Agency because long-term dermal exposure is not expected based on a one-time application as a seed treatment.

4. *Carcinogenicity*. In 1994, the Agency concluded that difenoconazole should be classed as a Group C carcinogen (possible human carcinogen) and recommended that, for the purpose of risk assessment, the MOE approach be used for the quantification of human risk. The decision to classify difenoconazole as a Group C carcinogen was based on statistically significant increases in liver adenomas, carcinomas, and combined adenomas and carcinomas in both sexes of CD–1 mice, but only at doses that were considered to be excessively high for carcinogenicity testing. The MOE approach was recommended because there was only very weak (limited) evidence of carcinogenic potential at dose levels not considered to be excessive, with significant changes observed only at excessive doses. In addition, there was no evidence of genotoxicity. However, to date the Agency has not defined the level of concern for cancer risk using the MOE approach. Therefore, a quantitative risk analysis was conducted utilizing the Q_1* approach. The Q_1* was determined to be 0.157 $(mg/kg/day)^{-1}$. This value incorporates the scaling factor and is based on the male mouse liver adenomas and/or carcinomas combined.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have previously been established (40 CFR 180.475) for the fungicide difenoconazole in or on the following raw agricultural commodities: Bananas, barley (grain only); eggs; the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep; milk; rye (grain only); sweet corn (fodder, forage, and grain) and wheat (forage, grain, and straw). The food risk analyses also included the pending residue tolerances for canola and sweet corn. The risk assessments conducted by EPA to assess food exposures were handled as follows. In the acute food risk analysis, present and proposed tolerance level residues and 100% crop treated (PCT) values were used in the calculation, producing a Theoretical Maximum Residue Contribution (TMRC). In the chronic and cancer food risk analyses, anticipated residues were used for most commodities, while reduced values for PCT were used for barley, sweet corn, and wheat. The PCT value used for barley is actually a percent crop imported value, because the barley residue tolerance is an import tolerance. Percent crop imported and PCT have equivalent effects on the calculations.

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.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, 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 section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows and believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic food exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. The percent imported data for barley were derived from statistics published by the National Agricultural Statistics Service and the Economic Research Service, both of which are units of the United States Department of Agriculture. A weighted average of the PCT reasonably represents a person's food exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute food exposure estimates, EPA uses estimated maximum PCTs (in this case 100%). The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. As to Conditions 2 and 3, 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.

A food exposure analysis using the Dietary Exposure Evaluation Model (DEEM) for the acute and both of the chronic (cancer and non-cancer) analyses evaluated individual food consumption as reported by respondents during the USDA 1989–1992 Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical from each commodity.

i. *Acute exposure and risk*. Acute food 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 endpoint used for all population subgroups that were analyzed in the acute food analyis was an aPAD of 0.25 mg/kg that incorporated Uncertainty Factors of 10x for interspecies extrapolation, 10x for intraspecies variability, and 1x for the FQPA Safety Factor. The subgroups analyzed and the exposure values calculated at the 95th percentile were females 13+ years old, pregnant, and not nursing—0.000852 mg/kg; females 13+ years old, nursing—0.000889 mg/kg; females 13–29 years old, not pregnant, not nursing—0.000750 mg/kg; females 20+ years old, not pregnant, not nursing—0.000668 mg/kg; females 13–50 years old—0.000701 mg/kg. In each case the exposure value is less than 1% of the aPAD. The exposure values calculated at the 99th percentile were females 13+ years old, pregnant, and not nursing—0.001093 mg/kg; females 13+ years old, nursing—0.001086 mg/kg; females 13–29 years old, not pregnant, not nursing—0.001008 mg/kg; females 20+ years old, not pregnant, not nursing—0.000987 mg/kg; females 13–50 years old—0.001008 mg/kg. In each of these cases the exposure value is also less than 1% of the aPAD. The exposure values calculated at the 99.9th percentile were females 13+ years old, pregnant, and not nursing—0.001265 mg/kg; females 13+ years old, nursing—0.001115 mg/kg; females 13–29 years old, not pregnant, not nursing—0.001570 mg/kg; females 20+ years old, not pregnant, not nursing—0.001359 mg/kg; females 13–50 years old—0.001436 mg/kg. Once again, in each of these cases the exposure value is less than 1% of the aPAD. The exposures were below the Agency's level of concern for all subgroups of females who were 13 to 50 years old. The Agency's level of concern is for exposures greater than 100% of the aPAD.

ii. *Chronic (non-cancer and cancer) exposure and risk*. For the chronic (non-cancer) food analysis, a cPAD of 0.01 mg/kg/day was used. It incorporated Uncertainty Factors of 10x for interspecies extrapolation and 10x for intraspecies variability, and an FQPA Safety Factor of 1x. The chronic (both cancer and non-cancer) analyses for difenoconazole are both partially refined estimates (Tier 3 assessments) because they use anticipated residues for all commodities and PCT information for some commodities.

The exposure estimates produced by the chronic (non-cancer) dietary exposure analysis are the following: U.S. population (48 states)—0.000005 mg/kg/day; all infants less than 1 year old—0.00016 mg/kg/day; nursing infants less than 1 year old—0.000007; non-nursing infants less than 1 year old—0.000016 mg/kg/day; children 1-6 years old—0.000011 mg/kg/day; children 7–12 years old—0.000005 mg/kg/day; females 13–19 years old, not pregnant, not nursing—0.000003 mg/kg/day; females 20+, not pregnant, not nursing—0.000004 mg/kg/day; females 13–50—0.000004 mg/kg/day; females 13+ years old, pregnant, nursing—0.000004 mg/kg/day; females (13+ years old, nursing—0.000006 mg/kg/day; non-Hispanic Whites—0.000006 mg/kg/day; non-Hispanic/non-White/non-Black—0.000006 mg/kg/day. In each case the exposure estimate is less than 1% of the cPAD.

The endpoint calculated for the chronic (cancer) analysis was a Q_1* of 0.157 $(mg/kg/day)^{-1}$. The result of the exposure analysis was that the exposure

for the U.S. population was estimated to be 0.000005 mg/kg/day. This exposure estimate produces a lifetime cancer risk estimate of 8.6×10^{-7}, below the Agency's 1×10^{-6} level of concern.

2. *From drinking water*. The Agency does not have the monitoring data available that is needed to perform a quantitative drinking water risk assessment for difenconazole at this time. Ground and surface water concentration estimates, for the parent chemical only, were therefore calculated. These estimates may be used qualitatively.

The Agency's Tier 1 models for estimating surface and ground water pesticide concentrations, GENEEC (Generic Estimated Environmental Concentration) and SCI-GROW (Screening Concentration in Ground Water), are not designed to estimate runoff or leaching values for seed treatment pesticides. Therefore, there are uncertainties in the predictive potential of the Tier 1 modeling. Additionally, it was necessary to use screened environmental fate data in the assessment because there was insufficient time to conduct a formal review of data that had previously been submitted by a predecessor company to Novartis Crop Protection, Inc. The uncertainties in the water assessment, however, are not expected to substantially decrease the conservativeness of the Tier 1 modeling results. The Tier 1 water modeling used in the instant analysis is the same as the analysis previously done for wheat. Because wheat is seeded at a much higher rate (by weight of seed) than canola, even more conservative estimates of resulting difenoconazole concentrations in ground and surface waters should result. Wheat is seeded at a rate of 60–120 pounds (lbs.) per acre, while canola is seeded at a rate of 5–10 lbs. per acre.

Therefore, the application rate of difenconazole used in the analysis is based on a wheat seed treatment rate of 0.025 lb. active ingredient (a.i.) per 100 lbs. of seed and the maximum seeding rate (120 lbs./acre). This produces a maximum application rate of 0.03 lb. difenconazole per acre. Based on the preliminary screen of the environmental fate data submitted by the registrant, difenoconazole is expected to be relatively immobile but persistent in terrestrial environments. The adsorption coefficients for difenoconazole that were used in these calculations were 12.76 microliters per gram (μL/g; producing a K_{oc} = 3,866) in an agricultural sand, 62.97 μL/g (K_{oc} = 3,470) in sandy loam soil, 54.84 μL/g (K_{oc} = 7,734) in silt loam soil, and 47.18 μL/g (K_{oc} = 7,734) in a silty clay loam soil. The aerobic soil metabolism half-life for difenoconazole ranged from 175 to 1,600 days. Difenoconazole had a first-order photodegradation half-life of 5.68 days in water.

GENEEC deals with surface water and models the results of a single runoff event (but can handle multiple spray-drift events, though spray drift is not a consideration in the instant analysis of a seed treatment fungicide) and manditorily represents an outdoor system consisting of a 10 hectare (ha) field immediately adjacent to a 1 ha pond that is 2 meters (m) deep and has no outlet. GENEEC allows reduction of the amount of pesticide that runs off by accounting for degradative processes in the field and soil-binding. However, limitations of this approach are that surface-source drinking water usually comes from bodies of water that are much larger than a 1-ha pond, the entire drainage basin (the 10-ha field) of the pond is assumed to receive an application of the pesticide (quite unlikely for a drinking water source), and most surface drinking water sources will have at least some water turnover (outflow, etc.). Despite this, GENEEC still allows screening calculations and the provision of an upper bound estimate (probably often a substantial overestimate) of surface water concentrations of a pesticide. Where the level of concern for drinking water concentrations is exceeded, the Agency can use various methods to refine the estimate.

SCI-GROW deals with ground water and is an empirical screening model based on actual ground water monitoring data collected from small-scale prospective ground water monitoring studies for the registration of a number of pesticides that serve as benchmarks for the model. The current version of SCI-GROW provides realistic estimates of pesticide concentrations in shallow, highly vulnerable (sandy soil and depth-to-ground-water of 10 to 20 feet) ground water, nearly a worst-case scenario for ground water contamination. There may be exceptional circumstances under which concentrations of a pesticide may exceed the SCI-GROW estimates but such circumstances should be rare. The ground water concentrations generated by SCI-GROW are based on the largest 90-day average concentration recorded during the sampling period. Because of the conservative nature of the monitoring data on which the model is based, SCI-GROW is considered to provide an upper bound estimate of pesticide residues in ground water. Since it is believed that pesticide concentrations in ground water do not fluctuate widely, SCI-GROW provides one estimate that is used both as a maximum and as an average concentration value in ground 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 with body weight variances. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide 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. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

The Agency's default bodyweights are 70 kg for males, 60 kg for females, and 10 kg for children. The Agency's default water consumption values are 2 liters (L) for males and females, and 1 L for children. The equation for the calculation is: DWLOC (micrograms/Liter) equals (water exposure (mg/kg/day) times body weight) divided by (consumption (Liters) times 10^{-3} milligrams/microgram).

i. *Acute exposure and risk*. The GENEEC model (Tier 1) estimate of the acute or peak Estimated Environmental Concentration (EEC) for difenoconazole in surface water was 0.125 parts per billion (ppb). The SCI-GROW model estimate of the concentration of difenoconazole in ground water was 0.00084 ppb. The Agency calculated DWLOCs for acute exposure to difenoconazole in surface and ground water for females 13-50 years old. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the DEEM analysis) was subtracted from the aPAD to obtain the acceptable acute exposure to difenoconazole in drinking water. DWLOCs were then calculated using the default body weights and drinking water consumption figures. The results were that the acute DWLOC for both the subgroup females (13+ years old, pregnant, and not nursing) and for the subgroup females (13+ years old, nursing), was 7,470 ppb. For the subgroup females (13-29 years old, not pregnant, and not nursing), the

subgroup females (20+ years old, not pregnant, non-nursing), and the subgroup females (13-50 years old) the DWLOC was 7,480 ppb.

ii. *Chronic (cancer and non-cancer) exposure and risk*. The GENEEC model (Tier 1) estimate of the chronic 56-day EEC was 0.048 ppb. Agency drinking water guidance calls for this value to be divided by 3 to obtain the value to use in the chronic risk assessment. Therefore, the surface water value used in the chronic risk assessment of difenoconazole was 0.016 ppb. The SCI-GROW model estimate of the concentration of difenoconazole in ground water was 0.00084 ppb.

The Agency calculated DWLOCs for chronic (non-cancer) exposure to difenoconazole in surface and ground water. To calculate the DWLOC for chronic exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from the DEEM analysis) was subtracted from the cPAD to obtain the acceptable chronic (non-cancer) exposure to difenoconazole. DWLOCs were then calculated using the default body weights and drinking water consumption figures. For the group U.S. population (48 states), the subgroup non- Hispanic Whites, and the subgroup non-Hispanic/non-White/non-Black, the DWLOC was 350 ppb. For the subgroup all infants less than 1 year old, the subgroup nursing infants less than 1 year old, the subgroup non-nursing infants less than 1 year old, the subgroup children 1-6 years old, and the subgroup children 7-12 years old, the DWLOC was 100 ppb. For the subgroup females (13-19 years old/not pregnant, non-nursing), the subgroup females (20+ years old/not pregnant, non-nursing), the subgroup females (13-50 years old), the subgroup females (13+ years old/ pregnant/non-nursing), and the subgroup females (13+ years old/ nursing), the DWLOC was 300 ppb. The population group U.S. population (48 states), all infant and children subgroups, all subgroups for females 13-50 years old, and any other population subgroup whose exposure exceeded that of the U.S. population group were included in this analysis.

The Agency calculated DWLOCs for chronic (cancer) exposure to difenoconazole in surface and ground water for the U.S. population group. To calculate the DWLOC for chronic (cancer) exposure relative to a carcinogenic toxicity endpoint (Q_1*), the chronic (cancer) dietary food exposure from the DEEM analysis was subtracted from the ratio of the negligible cancer risk (1×10^{-6}) to the Q_1* to obtain the acceptable chronic (cancer) exposure to difenoconazole in drinking water. DWLOCs were then calculated using the default body weights and drinking water consumption figures. The $DWLOC_{cancer}$ for the U.S. population group is 0.048 ppb.

3. *From non-dietary exposure*. Difenococonazole has no residential uses so non-dietary exposure is not a factor in the difenoconazole exposure/ risk analysis.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether difenococonazole 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, difenococonazole 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 difenococonazole has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. The acute aggregate exposure includes food and water. The acute risk scenario for difenoconazole for the 5 subgroups analyzed is as follows. For females (13+ years old/ pregnant/non-nursing) the aPAD was 0.25 mg/kg, the NOAEL was 25 mg/kg, the food exposure estimate from DEEM was 0.000852 mg/kg/day, the water exposure estimate was 0.249 mg/kg/day, the SCI-GROW ground water EEC estimate was 0.00084 ppb, the GENEEC surface water EEC estimate was 0.125 ppb, and the DWLOC was 7,470 ppb. For females (13+ years old/nursing) the aPAD was 0.25 mg/kg, the NOAEL was 25 mg/kg, the food exposure estimate from DEEM was 0.000889 mg/kg/day, the water exposure estimate was 0.249 mg/kg/day, the SCI-GROW ground water EEC estimate was 0.00084 ppb, the GENEEC surface water EEC estimate was 0.125 ppb, and the DWLOC was 7,470 ppb. For females (13-29 years old/ not pregnant/non-nursing) the aPAD was 0.25 mg/kg, the NOAEL was 25 mg/kg, the food exposure estimate from DEEM was 0.000750 mg/kg/day, the water exposure estimate was 0.249 mg/kg/day, the SCI-GROW ground water EEC estimate was 0.00084 ppb, the GENEEC surface water EEC estimate was 0.125 ppb, and the DWLOC was 7,480 ppb. For females (20+ years old/ not pregnant/non-nursing) the aPAD was 0.25 mg/kg, the NOAEL was 25 mg/kg, the food exposure estimate from DEEM was 0.000668 mg/kg/day, the water exposure estimate was 0.249 mg/kg/day, the SCI-GROW ground water EEC estimate was 0.00084 ppb, the GENEEC surface water EEC estimate was 0.125 ppb, and the DWLOC was 7,480 ppb. For females (13-20 years old) the aPAD was 0.25 mg/kg, the NOAEL was 25 mg/kg, the food exposure estimate from DEEM was 0.000701 mg/kg/day, the water exposure estimate was 0.249 mg/kg/day, the SCI-GROW ground water EEC estimate was 0.00084 ppb, the GENEEC surface water EEC estimate was 0.125 ppb, and the DWLOC was 7,480 ppb.

From the acute dietary (food only) risk assessments, high-end exposure estimates were calculated for the female 13-50 subgroups only. The percent aPADs were below the Agency's level of concern at the 95th percentile for all female 13-50 year old sugroups with all estimated acute dietary exposures <1% of the aPAD. The maximum estimated concentrations of difenoconazole in surface and ground water are less than the Agency's acute DWLOCs for difenoconazole as a contribution to acute aggregate exposure. Therefore, taking into account the uses proposed in this action, the Agency concludes with reasonable certainty that residues of difenoconazole in drinking water (when considered along with other sources of exposure for which the Agency has reliable data) would not result in unacceptable levels of acute aggregate human health risk at this time.

2. *Chronic (non-cancer) risk*. There are no registered or proposed residential uses of difenoconazole. Therefore, chronic (non-cancer) aggregate exposure will include risk from food and water only. The chronic (non-cancer) scenario for difenoconazole is as follows. For the U.S. population group the food exposure estimate (from the DEEM assessment) is 0.000005 mg/kg/day, the water exposure estimate (the cPAD minus the DEEM dietary exposure estimate) is 0.00995 mg/kg/day, the cPAD is 0.01 mg/kg/day, the ground

water concentration estimate (from SCI-GROW modeling) is 0.00084 ppb, the surface water concentration estimate (from GENEEC modeling) is 0.016 ppb, and the DWLOC is 350 ppb. For the subgroup females (13+ years old, nursing) the food exposure estimate is 0.000007 mg/kg/day, the water exposure estimate is 0.01 mg/kg/day, the cPAD is 0.01 mg/kg/day, the ground water concentration estimate is 0.00084 ppb, the surface water concentration estimate is 0.016 ppb, and the DWLOC is 300 ppb. For the subgroup non-nursing infants (< 1 year old) the food exposure estimate is 0.000019 mg/kg/day, the water exposure estimate is 0.00999 mg/kg/day, the cPAD is 0.01 mg/kg/day, the ground water concentration estimate is 0.00084 ppb, the surface water concentration estimate is 0.016 ppb, and the DWLOC is 100 ppb. Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to difenoconazole from food will utilize < 1% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. From the chronic (non-cancer) dietary (food only) risk assessments, the percent cPADs were below the Agency's level of concern for the U.S. population and all population subgroups. The estimated chronic dietary risk associated with the use of difenoconazole is below the Agency's level of concern. The estimated average concentrations of difenoconazole in surface and ground water are less than the Agency's chronic (non-cancer) DWLOCs for difenoconazole in drinking water as a contribution to chronic aggregate exposure. Aggregate chronic (non-cancer) risk estimates due to exposure to difenoconazole in both food and water are also below the Agency's level of concern. EPA therefore concludes that there is a reasonable certainty that no harm will result from aggregate exposure to difenoconazole residues.

3. *Aggregate cancer risk for U.S. population*. There are no registered or proposed residential uses for difenoconazole, so chronic (cancer) aggregate exposure/risk estimates are derived from food and water exposure only. The chronic (cancer) scenario is as follows. For the U.S. population group the food exposure estimate (from DEEM) is 0.000005 mg/kg/day, the water exposure estimate (negligible risk (1×10^{-6}) divided by the Q_1^* is 0.00000137 mg/kg/day, the Q_1^* is 0.157 $(mg/kg/day)^{-1}$, the ground water concentration estimate (from SCI-GROW modeling) is 0.00084 ppb, the surface water estimate (from GENEEC modeling) is 0.016 ppb, and the DWLOC is 0.048 ppb. From the chronic (cancer) dietary (food only) risk assessments, the estimated lifetime risk for the U.S. population was 8.6×10^{-7}, which is below the Agency's level of concern (generally 1×10^{-6}). The estimated average concentrations of difenoconazole in surface and ground water are less than the Agency's $DWLOC_{cancer}$ for difenoconazole in drinking water as a contribution to chronic (cancer) aggregate exposure. EPA therefore concludes that there is a reasonable certainty that no harm will result from aggregate chronic (cancer) exposure to difenoconazole residues.

4. *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 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 prenatal 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 interspecies and intraspecies 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. *Developmental toxicity studies*. Difenoconazole was administered to pregnant rats at dose levels of 0, 2, 20, 100, and 200 mg/kg/day from day 6 to day 15 of gestation. Statistically significant decreases in maternal body weight gain and feed consumption were observed during the dosing period at dose levels of 100 and 200 mg/kg/day. At 200 mg/kg/day the incidence of bifid or unilateral ossification of the thoracic vertebrae was significantly increased on a fetal basis. There were also significant increases in the average number of ossified hyoid and decreases in the numbers of sternal centers of ossification (per fetus per litter). The average number of ribs was significantly increased, with accompanying increases in the number of thoracic vertebrae and decreases in the number of lumbar vertebrae in this group. These findings at the highest dose tested (200 mg/kg/day) appear to be the result of maternal toxicity. The NOAEL for maternal toxicity was 20 mg/kg/day and the LOAEL for maternal toxicity was determined to be 100 mg/kg/day based on decreased body weight gains and decreased food consumption at 100 mg/kg/day and higher. The NOAEL for developmental toxicity was 100 mg/kg/day and the 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 the 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 lumber vertebrae in this group.

In a developmental toxicity study in rabbits, impregnated females (16 per dose) were orally administered difenoconazole at 0, 1, 25, and 75 mg/kg/day during days 7 through 19 of gestation. At 75 mg/kg/day, maternal toxicity was manifested as decreased body weight gain and food consumption; no maternal toxicity was observed at lower doses. Developmental toxicity, observed only at 75 mg/kg/day, was a slight nonsignificant increase in post-implantation loss and resorption per dose and a significant decrease in fetal weight. For maternal toxicity, the LOAEL of 75 mg/kg/day is based on decreases in body weight gain and food consumption; the NOAEL is 25 mg/kg/day. For developmental toxicity, the LOAEL of 75 mg/kg/day is based on increases in post-implantation loss and

resorption and decreases in fetal body weight; the NOAEL is 25 mg/kg/day. The increases in post-implantation loss and resorption are presumed to occur after a single exposure.

iii. *Reproductive toxicity study*. In a 2-generation reproduction study, difenoconazole was administered in the diet to male and female rats at 0, 25, 250, and 2,500 ppm (0, 1.25, 12.5, and 125 mg/kg/day, respectively). Statistically significant reductions in bodyweight gains of F_0 and F_1 males were observed at 2,500 ppm during days 70-77 and during the course of the study (terminal bodyweight minus day 0 bodyweight). Significant reductions in bodyweight gains of F_0 and F_1 females were seen during the pre-mating, gestation, and lactation periods. A dose-related, but non-statistically significant decrease in bodyweight gain was seen in F_0 at 250 ppm during days 70-77 prior to mating, days 0-7 of gestation, and days 7-14 of lactation. At 2,500 ppm, significant reductions in pup bodyweight were detected on days 0, 4 (pre- and post-culling), 7, 14, and 21 for males and females of both generations. There was a significant reduction in the bodyweight of F_1 male pups on day 21 in the 250 ppm group. The percentage of male pups in the F_1 generation surviving days 0-4 was significantly reduced in the 2,500 ppm group. For parental toxicity, the LOAEL of 250 ppm (12.5 mg/kg/day) is based on the decreased maternal bodyweight gain; 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 weight at day 21; the NOAEL is 25 ppm (1.25 mg/kg/day).

iv. *Prenatal and postnatal sensitivity*. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to difenoconazole. In the prenatal developmental toxicity study in rats, no evidence of developmental toxicity was seen even in the presence of maternal toxicity. In the developmental toxicity study in rabbits, developmental toxicity was seen in the presence of maternal toxicity at the highest dose tested. In the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

v. *Conclusion*. A complete toxicology data base exists for difenoconazole, and exposure data are complete or are estimated based on data that reasonably account for potential exposures. Taking into account the completeness of the data and the absence of any evidence of increased sensitivity, EPA determined that the additional tenfold safety factor for the protection of infants and children was not necessary.

2. *Acute risk*. An acute dose and endpoint were not chosen for the general population including infants and children because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose). Acute exposure/risk analyses were performed only for subgroups of females 13-50 years old.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to difenoconazole from food will utilize < 1% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to difenoconazole in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *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 residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants is understood. Plant metabolism studies were conducted on wheat, tomatoes, grapes, potatoes, and canola and found to be acceptable. The canola metabolism study was performed using a foliar treatment of difenoconazole on canola. The proposed use is a seed treatment. The results in these studies are consistent with foliar metabolism studies submitted and reviewed for wheat, tomatoes, and potatoes. The metabolic pathway in canola appears to proceed by hydrolysis of the ketal to the ketone followed by reduction of the ketone to the alkanol. The alkanol can be conjugated with sugars or the bridge linking the phenyl and triazole moities is cleaved, forming free triazole. The free triazole can be conjugated with serine to yield an intermediate which can be oxidatively deaminated to the lactic acid analogue and then degraded further. There was no evidence for a minor metabolic pathway via hydroxylation of the phenyl ring moiety.

Metabolism studies for a wheat seed treatment have been submitted and reviewed. The seed treatment metabolism studies had similar results to the foliar studies. Therefore, the Agency has translated the foliar canola studies to seed treatment and considers the nature of the residue in canola understood.

The nature of the difenoconazole residue in animals was considered understood for wheat and barley (PP 2F4107) only. It was concluded that for any future petition in which there is a greater potential for transfer of residues to meat and milk, additional animal metabolism studies would be required. Since the proposed use on canola is a seed treatment and canola is not a major feed item, there is not a greater potential for transfer of residues to meat and milk. Therefore, additional animal metabolism studies were not required for this action and the nature of the residue in animals is considered understood for this action.

B. Analytical Enforcement Methodology

For plants, the petitioner has submitted a copy of method AG-676, which is similar to the enforcement method for wheat (method 575). Therefore, an Independent Laboratory Validation (ILV) was not required. Acceptable recoveries were obtained for all matrices. Samples are homogenized and centrifuged in an ACN/hexane mixture. The resulting solution is then decanted and extracted repeatedly, then partially evaporated, and, finally, eluted and brought to volume. The sample is analyzed by gas chromatography with mass spectral detection (GC/MSD). The reported limit of quantitation (LOQ) is 0.01 ppm.

A Petition Method Validation (PMV) has been successfully completed for petitioner proposed residue method 676, so adequate enforcement methodology is available to enforce the tolerance expression. When this method is formally completed, it will be forwarded to the Food and Drug Administration (FDA) to be included in Pesticide Analytical Manual II (PAM II).

The petitioner proposed Method AG-544A, ''Difenoconazole (CGA-169374) Analytical Method for the Determination of CGA-169374 Residues in Dairy and Poultry Tissue, Eggs and Milk by Gas Chromatography,'' as the analytical enforcement method. The sample is extracted by homogenization with acetonitrile and concentrated ammonium hydroxide for 1 minute, the extract is filtered, the filtrate is diluted with water and saturated sodium chloride, partitioned twice, then cleaned up. The final sample is then analyzed by packed column gas chromatography (GC) using alkali flame ionization detection. The reported LOQ

for livestock tissue is 0.05 ppm and for milk is 0.01 ppm. The Agency concluded that Method AG-544A is adequate for the purpose of enforcing difenoconazole tolerances in animal commodities. A satisfactory ILV of the method was submitted and a satisfactory PMV was completed by the Agency's residue analysis laboratory. This method was forwarded to FDA to be included in PAM II.

These methods may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

A total of six field trials were submitted and reviewed. The residue levels of difenoconazole in canola seed were all less than the LOQ of 0.01 ppm. The submitted data indicate that the appropriate tolerance level for residues of difenoconazole in canola seed is 0.01 ppm.

No processing study is required for this tolerance petition. The maximum theoretical concentration factor for processing of canola seed to canola oil is 3x. Difenoconazole was applied to canola at an exaggerated rate of 3.6x (0.09 pounds of active ingredient per 100 pounds of seed) as a seed treatment at two locations. Residue levels for each location were below the LOQ of 0.01 ppm.

The petitioner had requested (in support of wheat use, PP 2F4107) 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. Based on a diet composed of 100% wheat raw agricultural commodities (RACs) and residues at the levels of the proposed tolerances, the maximum dietary burden for dairy cattle is estimated to be 0.30 ppm. Two metabolism studies were performed on ruminants (lactating goats) in a 10-day study with a dose rate of 4.17 ppm (14 x the 0.30 ppm estimated dietary burden) and a 3-day study with a dose rate of 100 ppm (333 x the 0.30 ppm estimated dietary burden). The total radioactive residue (TRR) in the goat tissues was used to estimate the expected residues in a feeding study with a dose rate of 0.30 ppm. The maximum residue observed was in liver, estimated to be at a level of 0.02 ppm from both metabolism studies. This value is 2.5 x below the LOQ of the proposed analytical enforcement method (0.05 ppm). The estimated residue in milk would be 0.5 ppb, 200 x below the method LOQ of 0.1 ppm. The Agency accepted the petitioner'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 request which could result in higher residues of concern in meat, milk, poultry, and eggs.

The proposed use in/on canola in this action does not appear to result in higher residues of concern in meat, milk, poultry, and eggs. The proposed use pattern (seed treatment) and low animal dietary feed consumption (canola meal only commodity consumed, 15% of diet) support the assumption of no increase in residues. Therefore, animal feeding studies are not required for this action with the same caveat that if, in the future, uses are proposed that result in higher residues in animal commodities, feeding studies will be required.

D. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican maximum residue limits for residues of difenoconazole in canola. Therefore, a compatibility issue is not relevant to the proposed tolerance.

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 rotational studies using phenyl-labeled difenoconazole. In the RACs 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 plant-back restrictions for all rotational crops. A 30-day plantback restriction for all crops is appropriate.

V. Conclusion

Therefore, a tolerance is established for residues of difenoconazole in or on canola, seed at 0.01 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301005 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 14, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301005, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 7, 2000.

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 amended by revising the introductory text of

paragraph (a) and alphabetically adding canola, seed to the table in paragraph (a) 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-[4-(4-chlorophenoxy)-2-chlorophenyl]-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
* * * * *	
Canola, seed	0.01
* * * * *	

* * * * *

[FR Doc. 00–23773 Filed 9–14–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301045; FRL–6742–6]

RIN 2070–AB78

Myclobutanil; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes a time-limited tolerance for combined residues of the fungicide myclobutanil in or on artichoke at 1.0 part per million (ppm), and peppers (bell and non-bell) at 1.0 ppm for an additional 2–year period. This tolerance will expire and is revoked on July 31, 2002. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on both artichoke and peppers. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 the Federal Insecticide, Fungicide, and Rodenticide Act.

DATES: This regulation is effective September 15, 2000. Objections and requests for hearings, identified by docket control number OPP–301045, must be received by EPA on or before November 14, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301045 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–9358; and e-mail address: deegan.dave@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301045. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of September 16, 1998 (63 FR 49472) (FRL–6025–1), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) it established a time-limited tolerance for the combined residues of myclobutanil in or on artichoke and peppers (bell and non-bell), each at a tolerance level of 1.0 ppm, with an expiration date of July 31, 2000. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Such tolerances can be established without providing notice or period for public comment.