ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[Docket# MA–068–7203c; FRL–6430–6]

Approval and Promulgation of State Plans For Designated Facilities and Pollutants: Massachusetts; Plan for Controlling MWC Emissions From Existing MWC Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; withdrawal.

SUMMARY: On July 14, 1999, EPA published a direct final rule (64 FR 37851) approving, and an accompanying proposed rule (64 FR 37923) proposing to approve, a State Plan submitted by the Commonwealth of Massachusetts on January 11, 1999. This State Plan, which is under sections 129 and 111(d) of the Clean Air Act, proposes provisions that are at least as protective as EPA's Emission Guidelines (EG). The EG are applicable to existing Municipal Waste Combustor (MWC) units with a capacity to combust more than 250 tons/day of municipal solid waste. *See* 40 CFR part 60, subpart Cb. EPA is withdrawing this direct final rule because adverse comments have been received. EPA will now consider, summarize and respond to any comments received before taking final action on the State Plan.

DATES: As of September 1, 1999, EPA withdraws the direct final rulemaking published on July 14, 1999.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA.

FOR FURTHER INFORMATION CONTACT: John J. Courcier, (617) 918–1659.

Dated: August 23, 1999.

John P. DeVillars,

Regional Administrator, Region 1.

[FR Doc. 99–22629 Filed 8–31–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300904; FRL–6094–3]

RIN 2070–AB78

Difenoconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of difenoconazole [[(2S,4R)/(2R,4S)/(2R,4R)/(2S,4S)]1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl]-1*H*-1,2,4-triazole] in or on sweet corn commodities. 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 sweet corn seed. This regulation establishes a maximum permissible level for residues of difenoconazole in these food and feed commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on January 31, 2001.

DATES: This regulation is effective September 1, 1999. Objections and requests for hearings must be received by EPA on or before November 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300904], 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–300904], 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 also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300904]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, 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. 271, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9356, beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the fungicide difenoconazole, in or on sweet corn seed, forage, and stover at 0.1 part per million (ppm). These tolerances will expire and are revoked on January 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Findings

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

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

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

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

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

II. Emergency Exemption for Difenoconazole on Sweet Corn Seed and FFDCA Tolerances

Idaho leads the nation in production of SH2 hybrid sweet corn seed, accounting for more than 90% of the total U.S. production. SH2 hybrids are used in the production of super sweet varieties of fresh market and processing sweet corn. In the past, captafol was used in combination with other registered fungicides as a sweet corn seed protectant. However, all captafol uses were voluntarily canceled in May of 1987 as a result of the captafol Special Review. According to the Applicant, the currently registered fungicides available for use on sweet corn provide only marginal control of dieback syndrome (brought on by fungal pathogens, *Penicillium*, *Pythium*, and *Fusarium* species) on hybrid sweet corn varieties. If difenoconazole is not available for use, stand reductions of 20–60% could occur, resulting in significant economic losses for Idaho's sweet corn seed producers, and sweet corn growers in other States, such as Florida where the disease problem is particularly severe. Prior to this year, Idaho received exemptions for use of another material, imazalil, for this situation; however, issues surfaced last year concerning imazalil and EPA could not make the safety finding as required under FQPA for the imazalil use. EPA has authorized under FIFRA section 18 the use of difenoconazole on sweet corn seed for control of fungal pathogens in Idaho. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of difenoconazole in or on sweet corn commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on January 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sweet corn commodities after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether difenoconazole meets EPA's registration requirements for use on sweet corn seed or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as basis for registration of difenoconazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Idaho to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for difenoconazole, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), 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 a time-limited tolerance for residues of difenoconazole on sweet corn seed, stover, and forage at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

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

B. Toxicological Endpoints

1. *Acute toxicity*. Based on the available acute toxicity data, EPA has determined that the no observable adverse effect level (NOAEL) of 25

milligrams per kilograms body weight per day (mg/kg/bwt/day) from the developmental study in rabbits should be used to assess risk from acute toxicity. Increases in post-implantation loss and resorption, decreases in fetal body weight, and decreases in body weight gains and food consumption in dams, were observed at the lowest obsevable adverse effect level (LOAEL) of 75 mg/kg/day. Using the uncertainty factors (UFs) of 10x for interspecies and 10x for intraspecies variations, the acute Reference Dose (RfD) is 0.25 mg/kg/day. The acute risk assessment will evaluate acute dietary risk to females 13+ years, the population subgroup of concern.

2. *Short- and intermediate-term toxicity.* For short-term Margin of Exposure (MOE) calculations, the developmental NOAEL of 25 mg/kg/day, from the developmental rabbit study will be used, with a dermal absorption factor adjustment of 75%. At the LOAEL of 75 mg/kg/day, there were increased post-implantation losses and resorptions per dose, a significant decrease in fetal body weight, and decrease in body weight gains and food consumption in the dams.

For intermediate-term MOE calculations, the NOAEL of 1.25 mg/kg/day from the 2–generation study in rats will be used. At the LOAEL of 12.5 mg/kg/day, there were decreased pup weights.

3. *Chronic toxicity*. EPA has established the RfD for difenoconazole at 0.01 mg/kg/day. This RfD is based on cumulative decreases in body weight gains at the LOAEL of 24.0 mg/kg/day from the chronic feeding/oncogenicity study in rats with a NOAEL of 0.96 mg/kg/day, and an uncertainty factor of 100.

4. *Carcinogenicity*. Difenoconazole has been classified as a Group C possible carcinogen, based on statistically significant increases in liver adenomas, carcinomas, and combined adenomas and carcinomas in both sexes of CD–1 mice, only at doses that were considered to be excessively high for carcinogenicity testing. The MOE approach was recommended for risk assessments, because there was only very weak evidence of carcinogenic potential at dose levels not considered to be excessive, with significant changes seen only at excessive doses. Additionally, there was no evidence of genotoxicity. However, at this time, the Agency has not defined the acceptable 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 calculated to be 1.57×10^{-1} (mg/kg/day)$^{-1}$.

C. Exposures and Risks

1. *From food and feed uses.* Permanent tolerances have been established (40 CFR 180.475) for the residues of difenoconazole, in or on wheat and livestock commodities ranging from 0.05 to 0.1 ppm and on bananas (import) at 0.2 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from difenoconazole as follows:

i. Acute exposure and risk. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. EPA's detailed acute analysis estimated the distribution of single-day exposures for the subgroup Females 13+ Years Old. An evaluation was not conducted for the overall U.S. population and infant and children subgroups, because oral toxicological studies did not demonstrate effects on these groups that could be attributable to a single dose exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. This acute exposure analysis was performed assuming tolerance level residues and 100% crop treated. Taking into account published and proposed tolerances (including these for sweet corn commodities), at the 95th percentile, the exposure utilized less than 1% of the RfD for the population subgroup of concern, Females 13+ Yrs. Old. Therefore, the level of concern is not exceeded.

ii. *Chronic exposure and risk.* The chronic risk assessment was conducted using mean consumption (3–day average) values, and was refined using anticipated residues and percent of crop treated (PCT) information for select commodities. The RfD of 0.01 mg/kg/day and an uncertainty factor of 100 were used. Since it was determined that the FQPA UF of 3x was not necessary, acceptable dietary exposure must not exceed 100% of the chronic RfD for all population subgroups. The Novigen DEEM system was used for this chronic dietary exposure analysis.The subgroups listed below are: (1) the U.S. Population (48 contiguous States); (2) those for infants and children; and, (3) the other subgroups (adult) for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. Population (48 contiguous States). The results are summarized below.

Population Subgroup	Exposure (mg/kg bwt/day)	% Chronic RfD
U.S. Population (48 contiguous States).	0.000005	< 1
All Infants (< 1 yr)	0.000016	< 1
Nursing Infants (<1 yr).	0.000007	< 1
Non-nursing Infants (<1 yr).	0.000019	< 1
Children (1–6 yrs)	0.000011	< 1
Children (7–12 yrs) ..	0.000005	< 1
Females (13+ yrs / Nursing).	0.000006	< 1
Seniors (55+ yrs)	0.000006	< 1
Non-Hispanic, Other than Black/White.	0.000006	< 1

As shown in the above table, chronic dietary risk does not exceed the level of concern for any of the population subgroups.

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). As previously explained in this document, a non-linear, MOE approach was recommended to quantify human cancer risk from difenoconazole. 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 cancer study in mice. The exposure analysis estimating potential cancer risks for difenoconazole was performed using anticipated residues and PCT or percent imported, as refinements, for selected commodities, to determine Estimated Lifetime Cancer Risk for the general population. The DEEM analysis was used, as described previously, and the partially refined exposure estimate calculated for the U.S. population (48 contiguous States) was 0.000005 mg/kg/day, translating to a lifetime cancer risk estimate of 8.4×10^{-7} from residues in food. This cancer risk estimate does not exceed the Agency's level of concern.

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 ppm for bananas; 0.000019 for eggs; 0.0000043 ppm for egg whites; 0.000046 ppm for egg yolks; 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 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:

Three PCT for sweet corn, 9 PCT 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) in this unit 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 are 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.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for difenoconazole. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on GENEEC and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and SCI-GROW, which predicts pesticide concentrations in ground water. None of these models include consideration of the impact that processing of raw water, for distribution as drinking water, would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to difenoconazole, they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Difenoconazole is not currently registered for use on any residential non-food sites. Therefore, there are no exposures and risks from non-dietary residential exposure.

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

EPA does not have, at this time, available data to determine whether 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 common mechanism of toxicity with other substances. For more 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.* From the acute dietary (food only) risk assessment, a high-end exposure estimate was calculated for the population subgroup of concern, Females 13+ years. For this group, less than 1% of the RfD is occupied by dietary (food only) exposure. This small percentage of the acute RfD utilized by this exposure provides assurance that there is reasonable certainty that no harm will result to both Females 13+ years, and to the prenatal development of infants. Acute effects for the general population are not expected.

The maximum estimated concentrations of difenoconazole in surface and ground water are less than the DWLOCs for difenoconazole as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of difenoconazole in drinking water will not contribute significantly to the aggregate acute human health risk.

2. *Chronic risk.* Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to difenoconazole from food will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (<1 yr. old), still at <1% of the RfD. This is further discussed below in the section on 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 concentrations of difenoconazole in surface and ground water are less than the DWLOCs for difenoconazole as a contribution to chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of difenoconazole in drinking water will not contribute significantly to the aggregate chronic human health risk. 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.

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, these risk assessments are not required.

4. *Aggregate cancer risk for U.S. population.* The DEEM dietary exposure analysis used anticipated residues and PCT information for selected commodities, to estimate the lifetime cancer risk for the general population. Using the dietary exposure estimate of 0.000005 mg/kg/day, the lifetime dietary cancer risk was calculated to be 8.4 x 10^{-7}. The estimated average concentrations of difenoconazole in surface and ground water are less than the DWLOCs for difenoconazole as a contribution to cancer aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues which may occur in drinking water do not contribute significantly to the aggregate chronic human health risk. Thus, aggregate cancer risk estimates associated with exposure to difenoconazole from food and water do not exceed levels of concern.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is 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 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 MOE and 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.* In a developmental study in rats, the NOAEL for maternal toxicity was 20 mg/kg/day, based upon statistically significant decreases in maternal body weight gain and feed consumption at the LOAEL of 100 mg/kg/day. The NOAEL for developmental toxicity was 100 mg/kg/day, based upon the incidence of bifid or unilateral ossification of the thoracic vertebrae, and significant increases in the average number of ossified hyoid and decreases in the number of sternal centers of ossification. 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. These effects were observed at the LOAEL of 200 mg/kg/day.

In a developmental study in rabbits, the NOAEL for maternal toxicity was 25 mg/kg/day, based upon decreases in body weight gain and food consumption seen at the LOAEL of 75 mg/kg/day. The developmental toxicity NOAEL was also 25 mg/kg/day, with increases in post-implantation loss and resorptions, and decreases in fetal body weight, seen at the LOAEL of 75 mg/kg/day.

iii. *Reproductive toxicity study.* In a 2–generation reproduction study in rats, the NOAEL for parental toxicity was 25 ppm (1.25 mg/kg/day), based upon decreased maternal body weight gain at the LOAEL of 250 ppm (12.5 mg/kg/day). The NOAEL for reproductive toxicity was also 25 ppm, based upon decreased pup weights at day 21, at the LOAEL of 250 ppm.

iv. *Prenatal and postnatal sensitivity.* The FQPA Safety Factor Committee recommended that the 10x safety factor for enhanced sensitivity to infants and children be reduced to a 1x factor, since the toxicology data base is complete, and there is no indication of increased susceptibility of rats or rabbit fetuses to prenatal or postnatal exposure.

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

2. *Acute risk.* An acute RfD is not established for the general population, including infants and children, because there were no effects observed in

toxicity studies (including maternal toxicity in the rabbit and rat developmental studies), which were attributable to a single exposure. Therefore, 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 <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, these risk assessments are not required.

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.

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residues of difenoconazole in plants and animals is considered to be adequately understood. Based on acceptable metabolism studies, the Agency concluded that none of the difenoconazole metabolites warrant inclusion in the tolerance regulation, separate regulation, inclusion in the dietary risk assessment, or additional metabolism or toxicological studies. Therefore, the residue of concern is the parent compound, difenoconazole per se, as specified in 40 CFR 180.475.

B. Analytical Enforcement Methodology

An adequate enforcement method (Method AG–575B, MRID# 428065–04) is available for enforcement purposes. The method is Gas-Liquid Chromatography, using a nitrogen/phosphorus detector, which has been validated for wheat, barley, and bananas. EPA expects that this method will be adequate for these proposed tolerances for sweet corn commodities as well.

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.

Residues of difenoconazole are not expected to exceed 0.1 ppm in/on corn, sweet (kernel + corn with husk removed); corn, sweet, forage; or corn, sweet, stover, as a result of the section 18 use. Secondary residues are not expected in animal commodities as a result of this use.

D. International Residue Limits.

There are pending Codex MRLs for this compound in Mexico for oat, wheat, and barley. There are MRLs for this compound in Australia for carrots (0.5 ppm), potatoes (0.02 ppm), and bananas (0.5 ppm). There are no Codex residue limits established for difenoconazole in/on the sweet corn commodities listed above, and thus harmonization is not an issue for this action.

E. Rotational Crop Restrictions.

There is a 30–day plantback restriction for all rotational crops.

V. Conclusion

Therefore, the tolerances are established for residues of difenoconazole [(2S,4R)/(2R,4S)/(2R,4R)/(2S,4S)]1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl]-1*H*-1,2,4-triazole in/on corn, sweet (kernel + corn with husk removed); corn, sweet, forage; and corn, sweet, stover at 0.1 ppm.

VI. 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 November 1, 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 rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300904] (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.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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.

IX. 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: August 13, 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. In § 180.475, by adding paragraph (b) to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of difenoconazole in connection with use of this pesticide under a section 18 emergency exemption granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Corn, sweet (kernel + corn with husk removed).	0.1	1/31/01
Corn, sweet, forage ..	0.1	1/31/01
Corn, sweet, stover ...	0.1	1/31/01

* * * * *

[FR Doc. 99–22635 Filed 8–31–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300903; FRL–6094–4]

RIN 2070–AB78

Cymoxanil; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the fungicide cymoxanil in or on dried hops at 1 part per million (ppm) for an additional 1½–year period. This tolerance will expire and is revoked on October 15, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on hops. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (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 FIFRA section 18.

DATES: This regulation becomes effective September 1, 1999. Objections and requests for hearings must be received by EPA, on or before November 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300903], 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–300903], 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 also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300903]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, 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. 280, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703 308–9364, pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of December 2, 1998 (63 FR 66459) (FRL–6038–5), which announced that on its own initiative under section 408 of the 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 residues of cymoxanil in or on dried hops at 1 ppm, with an expiration date of April 15, 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 FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of cymoxanil on hops for this year's growing season due to the continued need for control of downy mildew. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of cymoxanil on hops for control of downy mildew in Idaho and Oregon.

EPA assessed the potential risks presented by residues of cymoxanil in or on dried hops. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of December 2, 1998 (63 FR 66459). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 1½-year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on