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.

IV. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 29, 1998.

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. 346a and 371.

§ 180.472 [Amended]

2. In § 180.472, by amending paragraph (b) by changing for the commodities ''beet roots,'' ''beet tops,'' ''turnip roots,'' and ''turnip tops'' the date ''11/29/98'' to read ''6/30/00'' and by changing for the commodities ''citrus fruits crop group'' and ''dried citrus pulp'' the date ''12/31/98'' to read ''6/30/00''.

[FR Doc. 98–26903 Filed 10–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300742; FRL–6036–9]

RIN 2070–AB78

Cyproconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a permanent tolerance for residues of cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*-1,2,4-triazole-1-yl)butan-2-ol in or on coffee, bean, green. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

DATES: This regulation is effective October 7, 1998. Objections and requests for hearings must be received by EPA on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300742, 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–300742, 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@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300742]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, 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: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 2, 1997 (62 FR 35804)(FRL–5722–9), EPA, issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) 0E3875 for a tolerance by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by Norvartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.485 be amended by establishing a permanent tolerance for residues of the fungicide cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*-1,2,4-triazole-1-yl)butan-2-ol, in or on coffee, bean, green at 0.1 part per million (ppm). A time-limited tolerance for cyproconazole in or on coffee beans was established with an expiration date of July 1, 1997 in the **Federal Register** of September 27, 1995 (60 FR 49795)(FRL–4976–5). This rule will establish a permanent tolerance.

I. Risk Assessment and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is

reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of cyproconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*-1,2,4-triazole-1-yl)butan-2-ol on coffee, bean, green at 0.1 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 cyproconazole is discussed below.

1. *Acute studies.* Acute studies indicate that the technical grade of cyproconazole is in Toxicity Category III for acute oral, acute dermal and acute inhalation and in Toxicity Category IV for dermal irritation and eye irritation. There was no dermal sensitization.

2. *Subchronic toxicity testing.* i. A 90-day rat study, was conducted in which the levels of cyproconazole (95.7% purity) tested were 0, 20, 80, and 320 ppm (0, 1, 4, and 16 mg/kg/day). Cyproconazole inhibited body weight gain, increased blood sodium, increased liver weights and produced histological changes in the liver at the high dose. Increased blood creatinine and decreased calcium levels were observed at the high and low dose, but not at the mid-dose. Effects were reversed after cessation of dosing and a four week recovery period. Since these changes were not observed after the recovery period, they were considered treatment related. A No Observed Adverse Effects Level (NOAEL) for this study was therefore not attained but the NOAEL would be <1.0 mg/kg/day.

ii. A 13-week feeding study was conducted with dogs treated at 0, 20, 100, and 500 ppm cyproconazole (95.6% purity) in which the NOAEL was 20 ppm (0.8 mg/kg/day) and the Lowest Observed Adverse Effect Level (LOAEL) was 100 ppm (4 mg/kg/day) based on adverse liver effects. At the high dose, treatment related changes included slack muscle tone, depressed body weight gain, and decreases in bilirubin, total cholesterol, HDL-cholesterol, triglycerides, total protein and albumin. There were increases in platelet counts, alkaline phosphatase, gamma glutamyl transferase, absolute and relative liver weights, relative kidney weights, and relative brain weights. Liver toxicity was indicated by hepatomegaly.

iii. A 21-day dermal study was conducted, in which levels of cyproconazole (95.6% purity) tested in New Zealand white rabbits were 50, 250, and 1,250 mg/kg. The NOAEL was 250 mg/kg and the LOAEL was 1,250 mg/kg. Effects included depressed body weight gain and food consumption and increased levels of AST, creatinine and cholesterol.

3. *Chronic toxicity studies.* In a one-year dog study in which dogs were fed a diet containing cyproconazole (95% purity) at levels of 0, 30, 100, or 350 ppm, a NOAEL of 30 ppm (1.0 mg/kg/day) and an LOAEL of 100 ppm (3.2 mg/kg/day) was attained based on liver effects. Several clinical laboratory parameters indicated differences between the control and treated animals which were consistent with liver effects. Laminal eosinophilic intrahepatocytic bodies were observed in all males and two females at the high dose, and in one male at the mid-level dose. These changes were thought to represent adaptive hypertrophy of the endoplasmic reticulum. Relative kidney weights were increased in low and high dose females; cytochrome P450 was significantly increased in males and females at 350 ppm and females at 100 ppm.

4. *Carcinogenicity* i. A mouse carcinogenicity study was conducted in which cyproconazole (95.1% purity) at levels of 0, 5, 15, 100 or 200 ppm added to the diet of mice for 81 weeks (males) and 88 weeks (females) resulted in a NOAEL for systemic toxicity of 15 ppm (1.8 mg/kg for males and 2.6 mg/kg for females). The LOAEL was 100 ppm (13.2 mg/kg for males and 17.7 mg/kg for females) based on a significantly increased incidence of hepatic single cell necrosis and diffuse hepatocytic hypertrophy in both sexes. The effect was more severe in males than females. There was a decreased amount of testicular germinal epithelium in males at the high dose which corresponded to an increased incidence of flaccid testes. There was an increased incidence of liver adenomas and carcinomas in both sexes.

ii. A rat chronic/carcinogenicity study in which cyproconazole (95.6% purity) fed to rats (males for 118 weeks, females for 121 weeks) at 0, 20, 50 or 350 ppm (males: 0, 1.0, 2.2 and 15.6 mg/kg; females: 0, 1.2, 2.7 and 21.8 mg/kg) resulted in slightly decreased body weights in the high dose females and increased incidence of fatty infiltration of the liver in the high dose males. The NOAEL for systemic toxicity was 50 ppm. The LOAEL was 350 ppm. It was determined that the dose levels were inadequate for the assessment of the carcinogenic potential of cyproconazole in the rat. The HED Carcinogenicity Peer Review Committee recommended that this phase of the study be repeated. The committee classified cyproconazole as a quantitated Group B2 carcinogen with a Q1* of 0.30 $(mg/kg/day)^{-1}$ based on the absence of an adequate carcinogenicity study in rats and the structural relationship of cyproconazole to closely related analogues shown to have carcinogenic activity.

5. *Developmental toxicity* i. A rat developmental toxicity study was conducted in which cyproconazole (95.6% purity) was administered as a suspension by gavage to sperm-positive female rats at dose levels of 0, 6, 12, 24, or 48 mg/kg on days 6 through 15 of gestation. The NOAEL for maternal toxicity was 6 mg/kg and the LOAEL was 12 mg/kg based on decreased body weight gain during dosing. The NOAEL for developmental toxicity was 6 mg/kg. The LOAEL was 12 mg/kg based on the increased incidence of supernumerary ribs.

ii. In a rabbit developmental toxicity study, cyproconazole (95.6% purity) was administered by gavage to 16 Chinchilla rabbits on days 6 through 18 of gestation at 0, 2, 10, or 50 mg/kg. The NOAEL for maternal toxicity was 10

mg/kg (equivocal). The LOAEL was 50 mg/kg based on decreased body weight gain during dosing. Developmental effects were also evaluated. Hydrocephalus internus was observed in 1 fetus at each treatment level. Therefore, the NOAEL for developmental toxicity was set at < 2 mg/kg and the LOAEL was 2 mg/kg. The incidence was 0.85, 0.83, and 0.93 for the low, mid, and high dose fetuses and 0.09 for the historical control.

iii. A rabbit developmental toxicity study was conducted in which cyproconazole (94.8% purity) was administered by gavage to 18 inseminated New Zealand White rabbits once daily on days 6 through 18 of gestation at dose levels of 2, 10, or 50 mg/kg. The NOAEL for maternal toxicity was 10 mg/kg and the LOAEL was 50 mg/kg based on decreased body weight gain. There was also evidence of developmental toxicity. The NOAEL for developmental toxicity was 2 mg/kg and the LOAEL was 10 mg/kg based on the increased incidence of malformed fetuses and litters with malformed fetuses.

6. *Reproductive toxicity*. In a rat 2–generation reproduction study, technical cyproconazole (95.6% purity) was administered to 26 male and 26 female F_0 and F_1 rats per group for 10 and 12 weeks, respectively, during the pre-mating period via the diet at 0, 4, 20 or 120 ppm. Treatment of males continued for three weeks after termination of mating and females were treated until necropsy (post-weaning). The systemic NOAEL for parental toxicity was set at 20 ppm (1.7 mg/kg) based on liver effects at 10.6 mg/kg. For reproductive toxicity, the NOAEL was set at 120 ppm (10.6 mg/kg). The increased gestation length in the F_0 dams and decreased F_1 litter sizes were not considered treatment related.

7. *Mutagenicity*. Several mutagenicity studies were conducted. Mutagenicity potential of cyproconazole was tested in several studies considered acceptable by the Agency. Since the results of 2 chromosomal aberration assays indicated that cyproconazole is clastogenic, additional mutagenicity data were requested to address an identified heritable risk concern. For the potential to induce chromosome aberrations in Chinese hampster ovary (CHO) cells, cyproconazole was positive under nonactivated and activated conditions, which supports the evidence that cyproconazole is clastogenic in this test system. Cyproconazole was negative in *Salmonella*, mouse micronucleus, and SHE/cell transformation assays. A dominant lethal assay in rats was submitted which was negative. Based on this evidence, the concern for a possible heritable effect was not pursued.

8. *Metabolism*. In metabolism/pharmacokinetics studies, cyproconazole was shown to be extensively metabolized in the rat. Unchanged cyproconazole and 13 metabolites were isolated and identified and 35 metabolites were detected in the excreta. Excretion was relatively rapid with the majority of the radioactivity appearing in the feces as a result of biliary elimination. Residues were found in renal fat, adrenals, kidney and liver although no significant tissue radioactivity was observed at 168 hours post dose.

9. *Neurotoxicity*. There have been no clinical neurotoxic signs or other types of neurotoxicity observed in any of the evaluated toxicology studies. It was not recommended that a developmental neurotoxicity study be required for cyproconazole.

10. *Other toxicological considerations*. Cyproconazole has a complete data base and no other toxicological concerns have been identified in the evaluated studies.

B. Toxicological Endpoints

1. *Acute toxicity*. The Agency concluded that since developmental toxicity was induced in rats and rabbits by the oral route, the acute risk estimate should be performed using the NOAEL (2 mg/kg/day) for developmental toxicity in the oral rabbit study.

2. *Short - and intermediate - term toxicity*. Registration of cyproconazole for use on coffee is not proposed for the United States and domestic uses on turf and roses will be discontinued so short- and intermediate-exposure assessments are not relevant.

3. *Chronic toxicity*. EPA has established the reference dose (RfD) for cyproconazole at 0.01 milligrams/kilogram/day (mg/kg/day). This RfD is based on the chronic feeding study in dogs with a NOAEL of 1.0 mg/kg/day and an uncertainty factor of 100. The LOAEL was 3.2 mg/kg/day, based on hepatotoxicity and organ weight changes.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified cyproconazole as a Group B2 Carcinogen (Probable Human Carcinogen). It was recommended that for the purpose of risk characterization, a low-dose extrapolation methodology $Q1^* = 3.0 \times 10^{-1}$ $(mg/kg/day)^{-1}$ be used for the estimation of human risk.

C. Exposures and Risks

1. *From food and feed uses.* A time-limited tolerance was established (40 CFR 180.485) for the residues of cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*-1,2,4-triazole-1-yl)butan-2-ol, in or on coffee beans at 0.1 ppm. The tolerance expired on July 1, 1997. In today's action, a permanent tolerance will be established for residues of cyproconazole in or on coffee, bean, green at 0.1 ppm. Risk assessments were conducted by EPA to assess dietary exposures from cyproconazole as follows:

The RfD used in the dietary exposure analysis was 0.01 mg/kg/day based on a NOAEL of 30.0 ppm (1.00 mg/kg/day) from a 1–year dog feeding study with an uncertainty factor of 100 that demonstrated hepatotoxicity and organ weight changes at 3.2 mg/kg/day. The theoretical maximum residue contribution (TMRC) for the general population is 0.000002 mg/kg/day and for females, 20 years old and older, is 0.000003 mg/kg/day. The anticipated residue contributions (ARC) as percentage of the RfD are 0.018 and 0.028% for the general population and females 20 years old or older, respectively. The chronic analysis for cyproconazole is not a worst case estimate of dietary exposure, with all residues at anticipated levels and 100% of the commodities assumed to be treated with cyproconazole.

The upper bound cancer risk, based on a $Q1^*$ of 0.30 $(mg/kg/day)^{-1}$, was calculated to be 5.3×10^{-7}, contributed through the proposed use of cyproconazole in the production of imported coffee beans. The carcinogenic analysis used proposed anticipated residues without adjustment for percent crop treated information incorporated into the analysis.

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.

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary exposure endpoint of concern for cyproconazole is developmental (increased incidence of malformed fetuses and litters with malformed fetuses). For the population subgroup of concern, females 13+ years old, the calculated Margin of Exposure (MOE) value is 33,000. No anticipated residues were used in this assessment.

ii. *Chronic exposure and risk.* In conducting the chronic dietary (food only) risk assessment, anticipated residues were utilized. The proposed cyproconazole tolerance for coffee results in an ARC that is equivalent to <0.1% of the RfD for the U.S. population (48 states) and all other subgroups except non-nursing infants (<1 year old). The percent of RfD for non-nursing infants is 0 since coffee is not consumed by this subgroup.

iii. *Dietary cancer risk.* Cyproconazole is classified as a Group B2 carcinogen with a Q1* of 3.0×10^{-1} $(mg/kg/day)^{-1}$. Based on this figure, the upper bound cancer risk was calculated to be 5.3×10^{-7}, contributed through the use of cyproconazole on imported coffee.

2. *From drinking water.* There will be no exposure of the U.S. population from drinking water. Novartis Crop Protection, Inc. has agreed to suspend importation of cyproconazole and will suspend the sale of cyproconazole for all registered uses (turf and roses) in the United States after the current stock is depleted.

3. *From non-dietary exposure.* Cyproconazole is currently registered for use on the following non-food sites: turf and roses. The registrant of products containing cyproconazole has committed to stop importation of this chemical for these uses at this time. Risk from non-dietary exposure from these uses until current stocks of products are depleted is considered to be minimal since stocks are already low and use is not wide-spread.

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 cyproconazole 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, cyproconazole 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 cyproconazole 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.* Since there are no drinking water or non-dietary exposures, acute risk is from dietary exposure only. For dietary risk to the population subgroup of concern, females 13+ years old, the calculated MOE is 33,000. EPA has no concerns if the MOE is greater than 100 when the NOAEL used in calculating the MOE is taken from an animal study. Since the MOE value of 33,000 is much greater than 100, there are no acute dietary concerns.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to cyproconazole from food will utilize <0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is females (20+ years, not pregnant, not nursing). 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. Since there will be no potential for exposure to cyproconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyproconazole residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. No short- or intermediate-term risk is expected since there is no expectation of exposure from the proposed use of cyproconazole on coffee.

4. *Aggregate cancer risk for U.S. population.* The only risk from cancer is from dietary (food) exposure. The upper bound cancer risk was calculated to be 5.3×10^{-7}, contributed through the use of cyproconazole on imported coffee. The Agency does not consider this cancer risk to be of concern. Since there will be no exposure from water or non-dietary exposure, aggregate cancer risk will not exceed the upper bound cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyproconazole 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 cyproconazole, 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 gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.*— a. *Rats.* In the developmental study in rats, the maternal NOAEL was 6 mg/kg,

and the LOAEL was 12 mg/kg based on decreased body weight gain during dosing. The developmental NOAEL was 6 mg/kg and the LOAEL was 12 mg/kg based on the increased incidence of supernumerary ribs.

b. *Rabbits*. In the developmental toxicity study in rabbits, the maternal NOAEL was 10 mg/kg/. The LOAEL was 50 mg/kg based on decreased body weight gain during dosing. The NOAEL for developmental toxicity was set at <2 mg/kg and the LOAEL was 2 mg/kg.

c. *Rabbits*. In another rabbit developmental toxicity study, the NOAEL for maternal toxicity was 10 mg/kg and the LOAEL was 50 mg/kg based on decreased body weight gain. The NOAEL for developmental toxicity was 2 mg/kg and the LOAEL was 10 mg/kg based on the increased incidence of malformed fetuses and litters with malformed fetuses.

iii. *Reproductive toxicity study.—Rats*. In the 2–generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 1.7 mg/kg, based on liver effects at 10.6 mg/kg. For reproductive toxicity, the NOAEL was 10.6 mg/kg. The increased gestation length in the F_0 dams and decreased F_1 litter sizes were not considered treatment related.

iv. *Pre- and post-natal sensitivity*. The pre- and post-natal toxicology data base for cyproconazole is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies and the 2–generation reproductive toxicity study in rats.

v. *Conclusion*. EPA concludes that, although the rabbit data indicate increased sensitivity of the fetus, no increase in sensitivity is implicated for infants and children and therefore, an additional uncertainty factor on the RfD is not required given the fact that the fetal NOAEL of 2, which is less than the maternal NOAEL of 10 (and therefore an additional factor is already considered in the risk assessment process), is twice the NOAEL used for the RfD. There is no indication that an acute MOE of 100 is not adequate. These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or post-natal sensitivity. No additional uncertainty factor for increased sensitivity in infants and children is appropriate. There is a complete toxicity database for cyproconazole and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. Since there are no drinking water or non-dietary exposures, acute risk is from dietary exposure only. For dietary risk, the MOE is calculated to be 33,000 for the most highly exposed subgroup , females 13+ years old. Since coffee is not generally consumed by infants and children, the MOE would be even greater for this group.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to cyproconazole from food will utilize 0% (non-nursing infants <1 year old) and <0.1% of the RfD from dietary exposure for children 1–6 years old and for the U.S. population. 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. Since there will be no potential for exposure to cyproconazole 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*. No short- or intermediate-term risk is expected since there is no expectation of exposure from the proposed use of cyproconazole on coffee.

5. *Cancer risk*. The only risk from cancer is from dietary (food) exposure. The upper bound cancer risk was calculated to be 5.3×10^{-7}, contributed through the use of cyproconazole on imported coffee. The Agency does not consider cancer risk to be of concern for estimates below approximately 1×10^{-6}. Since there will be no exposure from water or non-dietary exposure, aggregate cancer risk will not exceed the upper bound cancer risk.

6. *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 cyproconazole residues.

III. Other Considerations

A. Metabolism In Plants and Animals

1. *Plants*. The nature of the residue in coffee is fully understood. Cyproconazole per se was the primary component of the residue and is the only residue of regulatory concern. Similar results were observed in apples, grapes and coffee.

2. *Animals*. Cyproconazole was shown to be extensively metabolized in the rat. Unchanged cyproconazole and 13 metabolites were isolated and identified and 35 metabolites were detected in the excreta. Excretion was relatively rapid with the majority of the radioactivity appearing in the feces as a result of biliary elimination. Residues were found in renal fat, adrenals, kidney and liver although no significant tissue radioactivity was observed at 168 hours after treatment.

B. Analytical Enforcement Methodology

An adequate analytical method is available for enforcement purposes. Residues are quantified by gas chromatography equipped with a nitrogen-phosphorus detector. The limit of quantification is 0.01 ppm. The analytical method, AM–0822–1288–0, is available in the Pesticide Analytical Manual, Vol. II.

C. Magnitude of Residues

The average cyproconazole residue in green coffee beans in submitted studies was 0.026 ppm. The concentration of cyproconazole residues in roasted or instant coffee was not of sufficient magnitude to require separate tolerances for these commodities but concentration factors were used to calculate anticipated residues. The anticipated residues in roasted coffee beans were 0.038 ppm and 0.033 ppm for instant coffee. The residues in coffee will not exceed the proposed tolerance of 0.1 ppm.

D. International Residue Limits

There are no Codex, Canadian or Mexican residue limits established for cyproconazole on coffee. Therefore, no compatibility problems exist for the proposed tolerance on coffee.

E. Rotational Crop Restrictions

Rotational crop studies are not required for uses of pesticides on coffee.

IV. Conclusion

Therefore, the tolerance is established for residues of cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazole-1-yl)butan-2-ol in coffee, bean, green at 0.1 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 4– . However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications

can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 7, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee or a request for a fee waiver as prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments may be sent directly to EPA at: opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300742. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of

the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

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

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 29, 1998.

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. 346a and 371.

2. Section 180.485 is revised to read as follows:

§ 180.485 Cyproconazole; tolerances for residues.

(a) *General.* A tolerance is established for residues of the fungicide cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*-1,2,4-triazole-1-yl)butan-2-ol in or on the imported agricultural commodity coffee, bean, green at 0.1 ppm. There are no U.S. registrations as of October 7, 1998, for use on coffee beans.

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

(c) *Tolerances with regional registrations.* [Reserved]

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

[FR Doc. 98–26904 Filed 10–6–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300727; FRL–6033–7]
RIN 2070–AB78

Avermectin; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the insecticide and miticide avermectin and its metabolites in or on basil at 0.05 parts per million (ppm) for an additional 16 month period, to January 31, 2000. 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 basil. 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 section 18 of FIFRA.

DATES: This regulation becomes effective October 7, 1998. Objections and requests for hearings must be received by EPA, on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300727], 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–300727], 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@epamail.epa.gov. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Rosenblatt, 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 22202, (703) 308–9375; e-mail: rosenblatt.dan@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of October 29, 1997 (62 FR 56082) (FRL–5750–8), which announced that on its own initiative and under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established a time-limited tolerance for the residues of avermectin and its metabolites in or on basil at 0.05 ppm, with an expiration date of September 30, 1998. 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 FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of avermectin on basil for this year's growing season due to the damage to the crop in California from the leafminer. Female leafminers feed off and lay eggs within the leaf tissue of basil plants. The developing larvae also feed on the