Arlington, VA 22202. Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number, [PP 0E3875/P623]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-6900; e-mail:

welch.connie@epamail.epa.gov. SUPPLEMENTARY INFORMATION: EPA is proposing to establish an import tolerance for the residues of the fungicide cyproconazole, (2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazole-1-yl)butan-2-ol, in or on the raw agricultural commodity coffee beans at 0.1 part per million (ppm). The proposed regulation to establish a maximum permissible level of the fungicide pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, by amending 40 CFR part 180 to include this commodity was requested in a pesticide petition (PP 0E3875) submitted by Sandoz Agro, Inc., 1300 East Touhy Ave., Des Plaines, IL 60018.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerance include the following:

1. A 90-day rat study, in which the levels tested in Han Wistar strain rats were 0, 20, 80, and 320 ppm (0, 1, 4, and 16 mg/kg). 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 4-week recovery period. Since these changes were not observed after the recovery period they were considered treatment related. A NOEL for this study was therefore not attained, but the NOEL would be less than 1.0 mg/kg.

2. A 13-week feeding study in dogs treated at 0, 20, 100, and 500 ppm yielded a NOEL of 20 ppm (0.8 mg/kg/ day) and an LEL of 100 ppm (4 mg/kg/ day). 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.

3. A 21-day dermal study, in which levels tested in New Zealand white rabbits were 50, 250, and 1,250 mg/kg. The NOEL was 250 mg/kg and the LEL was 1,250 mg/kg. Effects included depressed body weight gain and food consumption and increased levels of AST, creatinine, and cholesterol.

4. A 1-year dog study. When dogs were fed a diet containing cyproconazole at levels of 0, 30, 100, or 350 ppm for one year, a NOEL of 30 ppm (1.0 mg/kg/day) and an LEL of 100 ppm (3.2 mg/kg/day) were attained. Several clinical laboratory parameters indicated a difference between the control and treated animals which was 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.

5. A mouse carcinogenicity study in which cyproconazole at levels of 0, 15, 100, or 200 ppm added to the diet of CD-1 mice for 81 weeks (males) and 88 weeks (females) resulted in a NOEL for systemic toxicity of 15 ppm (1.8 mg/kg for males and 2.6 mg/kg for females). The LEL 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 at the two highest levels. 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.

6. A rat chronic/carcinogenicity study in which cyproconazole fed to KFM Wistar (HAN Wistar origin) rats (males for 118 weeks, females for 121 weeks) at 0, 20, 50, or 350 ppm (males: 1.0, 2.2, and 15.6 mg/kg; females: 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 NOEL for systemic toxicity was 50 ppm. The LEL 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.

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

8. A chinchilla rabbit developmental toxicity study in which cyproconazole (95.6% purity) was administered by gavage to 16 Chinchilla rabbits on days 6 through 18 of gestation at 0, 2, 10, or