commodity cottonseed at 0.02 part per million (ppm). The Rohm & Haas Co. requested establishment of this tolerance.

**EFFECTIVE DATE:** This regulation became effective on March 30, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4317/ R2125], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections 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 objections and requests for hearings filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and requests for hearings must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and requests for hearings will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and requests for hearings in electronic form must be identified by the docket number [PP 4F4317/R2125]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and requests for hearings on this 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 issued a notice, published in the Federal Register of February 8, 1995 (60 FR 7539), which announced that the Rohm & Haas Co., Independence Mall West, Philadelphia, PA 19105, was proposing the establishment of a tolerance of 0.02 part per million (ppm) in pesticide petition (PP) 4F4317 for the residues of the fungicide myclobutanil, [alpha-butyl-alpha-(3-hydroxybutyl)-1H-1,2,4-triazole-1-propanenitrile, and both the free and bound forms of its metabolite, alpha-(3-hydroxybutyl)alpha-(4-chlorophenyl)-1H-1,2,4triazole-1-propanenitrile, in or on the raw agricultural commodity cottonseed. There were no comments received in response to the Federal Register notice. The data submitted in support of the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerance is sought. The toxicological data considered in support of the tolerance include the following:

1. A 1-year dog feeding study using doses of 0, 10, 100, 400, and 1,600 ppm (equivalent to doses of 0, 0.34, 3.09, 14.28 and 54.22 milligrams/kilogram (mg/kg) body weight (bwt)/day in males and 0, 0.40, 3.83, 15.68 and 58.20 mg/ kg bwt/day in females). The noobserved-effect level (NOEL) is 100 ppm (3.09 mg/kg/day for males and 3.83 mg/ kg/day for females) based upon hepatocellular hypertrophy, increases in liver weights, "ballooned" hepatocytes, and increases in alkaline phosphatase, SGPT and GGT, and possible slight hematological effects. The lowestobserved-effect level (LOEL) is 400 ppm (14.28 mg/kg/day for males and 15.68 mg/kg/day for females).

2. A 2-year chronic feeding/ carcinogenicity study in rats using dietary concentrations of 0, 50, 200 and 800 ppm (equivalent to doses of 0, 2.49, 9.84 and 39.21 mg/kg bwt/day in males and 0, 3.23, 12.86 and 52.34 mg/kg bwt/ day in females). The NOEL for chronic effects other than carcinogenicity is 2.49 mg/kg/day, and the LOEL is 9.84 mg/kg/ day based on testicular atrophy in males. No other significant effects were observed in either sex at the stated dose levels over a 2-year period. In addition, no carcinogenic effects were observed in either sex at any of the dose levels tested. Based on the toxicological findings, the maximum tolerated dose (MTD) selected for testing (based on the 90-day feeding study) was not high enough to fully characterize the compound's carcinogenic potential.

The study was repeated at dose levels of 0 and 2,500 ppm (125 mg/kg/day) in the diet, which approaches the MTD, in order to characterize the carcinogenic

potential. At 2,500 ppm the observed effects included: decreases in absolute and relative testes weights, increases in the incidences of centrilobular to midzonal hepatocellular enlargement and vacuolation in the liver of both sexes, increases in bilateral aspermatogenesis in the testes, increases in the incidence of hypospermia and cellular debris in the epididymides, and increased incidence of arteritis/ periarteritis in the testes. In this study, a NOEL could not be established because there were effects at the only dose level tested. Myclobutanil was not oncogenic when tested under the conditions of the study.

3. A 2-year carcinogenicity study in mice using dietary concentrations of 0, 20, 100, and 500 ppm (equivalent to 0, 2.7, 13.7, and 70.2 mg/kg/day in males and 0, 3.2, 16.5, and 85.2 mg/kg/day in females). The NOEL for chronic effects other than carcinogenicity was 20 ppm (2.7 mg/kg/day in males and 3.2 mg/kg/ day in females). The LOEL was 100 ppm (13.7 mg/kg/day in males and 16.5 mg/ kg/day in females) based on a slight increase in liver mixed-function oxidase (MFO). Microscopic changes in the liver were evident in both sexes at 500 ppm (70.2 mg/kg/day in males and 85.2 mg/ kg/day in females). There were no carcinogenic effects in either sex at any dose level tested. The highest selected dose was satisfactory for evaluating carcinogenic potential in male mice but was lower than the MTD in females.

The above study was reevaluated since the increase in the MFO at 3 months in females was not considered to be significant enough to establish an LOEL. The LOEL was raised to 500 ppm (70.2 mg/kg/day for males and 85.2 mg/ kg/day for females) based on increases in MFO in both sexes, increases in SGPT values in females and in absolute and relative liver weights in both sexes at 3 months, increased incidences and severity of centrilobular hepatocytic hypertrophy, Kupffer cell pigmentation, periportal punctate vacuolation and individual hepatocellular necrosis in males, and increased incidences of focal hepatocellular alteration and multifocal hepatocellular vacuolation in both sexes. The NOEL has been raised to 100 ppm (13.7 mg/kg/day for males and 16.5 mg/kg/day for females).

An 18-month study was conducted with female mice using a dose level of 2,000 ppm, which approaches the MTD, to evaluate the carcinogenic potential in female mice. In this study, a NOEL could not be established because there were effects at the only dose level tested. These effects included: decreases in body weight and body weight gain, increases in liver weights,