depression, decreased hemoglobin, hematocrit, MCV and MCHC, and increased liver microsomal enzymes in females. Tebuconazole was not oncogenic at the dose levels tested (0, 100, 300, and 1,000 ppm).

5. A rat oral developmental toxicity study with a maternal NOEL of 30 mg/ kg bw/day and an LEL of 60 mg/kg bw/ day based on elevation of absolute and relative liver weights. For developmental toxicity, a NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day was determined, based on delayed ossification of thoracic, cervical, and sacral vertebrae, sternum, fore and hind limbs and increase in supernumerary ribs.

6. A rabbit oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 100 mg/ kg bw/day based on depression of body weight gains and food consumption. A developmental NOEL of 30 mg/kg bw/ day and an LEL of 100 mg/kg bw/day were based on increased postimplantation losses, from both early and late resorptions and frank malformations in eight fetuses of five litters.

7. A mouse oral developmental toxicity study with a maternal NOEL of 10 mg/kg bw/day and an LEL of 20 mg/ kg bw/day based on a supplementary study indicating reduction in hematocrit and histological changes in liver. A developmental NOEL of 10 mg/kg bw/ day and an LEL of 30 mg/kg bw/day based on dose-dependent increases in runts/dam at 30 and 100 mg/kg bw/day.

8. A mouse dermal developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and a LEL of 60 mg/ kg bw/day based on a supplementary study indicating increased liver microsomal enzymes and histological changes in liver. The NOEL for developmental toxicity in the dermal study in the mouse is 1,000 mg/kg bw/ day, the highest dose tested (HDT).

9. A two-generation rat reproduction study with a dietary maternal NOEL of 15 mg/kg bw/day (300 ppm) and a LEL of 50 mg/kg bw/day (1,000 ppm) based on depressed body weights, increased spleen hemosiderosis, and decreased liver and kidney weights. A reproductive NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/ day (1,000 ppm) were based on neonatal birth weight depression.

10. An Ames mutagenesis study in *Salmonella* that showed no mutagenicity with or without metabolic activation.

11. A micronucleus mutagenesis assay study in mice that showed no genotoxicity. 12. A sister chromatid exchange mutagenesis study using CHO cells that was negative at dose levels 4 to 30 ug/ mL without activation or 15 to 120 ug/ mL with activation.

13. An unscheduled DNA synthesis (UDS) study that was negative for UDS in rat hepatocytes.

Additionally, a mouse oncogenicity study at dietary levels of 0, 20, 60, and 80 ppm for 21 months did not reveal any oncogenic effect for tebuconazole at any dose tested. Because the Maximum Tolerated Dose (MTD) was not reached in this study, the study was classified as supplementary. A followup mouse study at higher doses (0, 500, 1,500 ppm in the diet), with an MTD at 500 ppm, revealed statistically significant incidences of hepatocellular adenomas and carcinomas in males and carcinomas in females. The initial and followup studies, together with supplementary data submitted by Miles, Inc., were classified as core minimum

The Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (CPRC) has classified tebuconazole as a Group C carcinogen (possible human carcinogen). This classification is based on the Agency's "Guidelines for Carcinogen Risk Assessment" published in the Federal Register of September 24, 1986 (51 FR 33992). The Agency has chosen to use the reference dose calculations to estimate human dietary risk from tebuconazole residues. The decision supporting classification of tebuconazole as a possible carcinogen (Group C) rather than a probable carcinogen (Group B) was primarily based on the statistically significant increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of NMRI mice both by positive trend and pairwise comparison at the HDT, and the structural correlation with at least six other related triazole pesticides that produce liver tumors.

The Reference Dose (RfD) is established at 0.01 mg/kg of body weight (bwt)/day, based on a noobserved-effect level (NOEL) of 1.00 mg/ kg bwt/day and an uncertainty factor of 100. The NOEL is based on a 1-year dog feeding study that demonstrated lenticular and corneal opacity and hepatic toxicity as an endpoint effect. A chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. The Theoretical Maximum Residue Contribution

(TMRC) from the current action is estimated at 0.000078 mg/kg bwt/day and utilizes 0.78% of the RfD for the general population of the 48 States. The TMRC for the most highly exposed subgroup, nonnursing infants (less than 1 year old), is estimated at 0.000097 mg/ kg/day and utilizes less than 1% of the RfD.

The nature of the residue in barley, oats, and wheat is adequately understood. An adequate analytical method using high-performance liquid chromatography is available for enforcement purposes.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, **Environmental Protection Agency**, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232.

Tolerances for tebuconazole in or on animal commodities are not currently required.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the 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 prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the