in vivo cytogenetics assay using bone marrow from treated rats. No increase in unscheduled DNA synthesis in rat primary hepatocyte study was observed.

14. A rat metabolism study showed that radiolabeled fenbuconazole is rapidly absorbed, distributed, and excreted following oral administration in rats. Biliary excretion data indicated that systemic absorption of fenbuconazole was high for all dosing groups. The feces was the major route of excretion. Tissue distribution and bioaccumulation of fenbuconazole appeared to be minimal.

The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of fenbuconazole in mice and rats and has classified fenbuconazole as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the Federal Register in 1986 (51 FR 33992, Sept. 24, 1986) and recommended that for the purpose of risk characterization a low-dose extrapolation model applied to the experimental animal tumor data should be used for quantification for human risk (Q1*). This decision was based on the induction of thyroid follicular cell adenomas and/or combined adenomascarcinomas in male rats in two studies, both by pair-wise comparison with controls and by trend analysis. The studies were combined for the purpose of deriving the Q1*. The Q1* for fenbuconazole is 1.65 X 10-2 (mg/kg/ day)-1 in human equivalents.

Based on assumptions that 100 percent of the pecan crop is treated and that residues are at the tolerance level, the upper-bound limit of the dietary carcinogenic risk for pecans is calculated in the range of 1 incidence in 100 million (9.0 X 10-9). Based on assumption that stone fruit residues (except plums and prunes) are at the tolerance level and the limitation of production of the only fenbuconazole product registered under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) for use on stone fruit to 28,500 pounds of active ingredient per year (calculated to be equivalent to treating 12.8% of the total U.S acreage of apricots, cherries, nectarines, and peaches per year), the upper-bound limit of the dietary carcinogenic risk for stone fruit group except plums and prunes is calculated in the range of 1 incidence in 1 million (1 X 10-6).

Processing studies for pecans and stone fruit other than plums and prunes are not required. Therefore, food/feed additive tolerances are not needed in conjunction with these uses.

Using the NOEL of 3.0 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100fold safety factor, the Reference Dose (RfD) for systemic effects is 0.03 mg/kg/ day. The theoretical maximum residue contribution (TMRC) from the proposed tolerances is 0.000604 mg/kg/day and utilizes 2 percent of the RfD for the overall U. S. population. For exposure of the most highly exposed subgroups in the population, nonnursing infants (less than 1 year old), the TMRC is 0.00516 mg/kg/day and utilizes 17 percent of the RfD.

The metabolism of fenbuconazole in plants is adequately understood. Due to a chemistry data gap for storage stability of fenbuconazole in other raw agricultural commodities [GLN 171-4(e)], EPA believes it is inappropriate to establish permanent tolerances for the uses of fenbuconazole at this time. However, based on apparent storage stability, EPA believes that the existing data support time-limited tolerances to December 31, 1998.

The nature of the residue in plants is adequately understood for the purposes of these time-limited tolerances. An analytical method, gas-liquid chromatography with a thermionicspecific detector with nitrogen selectivity, 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).

There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no livestock feed items associated with this action. The pesticide is considered useful for the purpose for which the tolerance is sought. Based on the information and data considered, the Agency has determined that the time-limited tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are 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 and/or request a hearing 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 fees provided 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, and the requestor's contentions on each such issue, and a summary of the evidence relied upon by the objection (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 a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve on 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32)

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.