conclusion was based on the following: (1) There was no progression of benign tumors (adenomas) to malignancy (carcinomas); (2) there was no increase in hyperplastic changes; (3) there was no dose-response relationship; and (4) the two reevaluations of the microscopic slides by the pathologists at EPL and TB in OPP further did not confirm any apparent effects observed in the original report.

The issue of a possible treatment-related increase of adrenal medullary gland tumors, namely, pheochromocytomas, in the male rat was also reassessed by both CAG and the Peer Review Committee. Both concluded that the data, especially in view of the reevaluation of the microscopic slides performed by EPL, did not support a compound-related increase of adrenal medullary tumors; the incidence of pheochromocytomas more accurately represented spontaneous variations of a commonly occurring tumor in the aged rat.

The analysis of the significance of the equivocal increase in the incidence of liver tumors in male mice was very similar to that performed for the rat thyroid and adrenal gland tumors. The original pathological reading of the tissue slides reported an elevated increase of tumors in some treatment groups; however, these increases were not evident after a reevaluation of themicroscopic slides was performed by an independent pathologist at EPL and by the reading of a CAG pathologist. The Peer Review Committee concurred that the reevaluation of the slides is reliable and does not show any compound-related increase in the incidence of liver tumors in the mouse.

The Agency believes that the data from the rat and mouse long-term studies are sufficient to support the conclusion that metalaxyl does not show a carcinogenic potential in laboratory animals. This conclusion is supported by the following: (1) The doses tested in both the rat and mouse long-term studies approached an MTD based upon compound-related changes in liver weight and/or liver histology; (2) extensive available mutagenic evidence indicates no potential genotoxic activity which correlates with the negative carcinogenic potential demonstrated in long-term testing; (3) metalaxyl is not structurally related to known carcinogens; and (4) under the conditions of the rat and mouse tests, no indication of compound-related carcinogenic effects was noted at any of the treatment doses, sexes, or species.

The reference dose (RfD), anticipated residue contribution (ARC), and food additive regulations are covered by existing tolerances.

The nature of the residue is adequately understood. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume 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 Highway, Arlington, VA 22202, (703)-305-5232.

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

Based on the information and data considered, the Agency has determined that the tolerances 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 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 requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP 2F4105/R2191] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as (CBI), is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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 all comments 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 address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866, EPA must judge whether a rule is ''major'' and therefore requires a Regulatory Impact Analysis. This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12866.

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: December 4, 1995.