lesions in males at 300 ppm (16.9 mg/kg/day) and above, and in females at 900 ppm (73 mg/kg/day) and above. There were no apparent carcinogenic effects under the conditions of the study.

3. A 2-year carcinogenicity study in mice fed diets containing 0, 100, 330, 1,000, or 2,000 ppm with a NOEL of 1,000 ppm (208 mg/kg/day in males, 274 mg/kg/day in females) based on decreased food consumption and decreased water intake at the 2,000-ppm dose level. There were no apparent carcinogenic effects observed under the conditions of this study.

4. A three-generation reproduction study with rats feed diets containing 0, 100, 250, or 700 ppm with a reproductive no-observed-effect level (NOEL) of 100 ppm (equivalent to 8 mg/kg/day based on decreased pup body weight observed at the 250-ppm dose level.

5. A developmental toxicity study in rat given gavage doses at 0, 10, 30, or 100 mg/kg/day during gestation days 6 to 16 with a NOEL for developmental toxicity at 30 mg/kg/day based on increased wavy ribs observed at the 100 mg/kg/day dose level.

6. A developmental toxicity study in rabbits given gavage doses at 0, 8, 24, or 72 mg/kg/day during gestation days 6 through 19 with a NOEL for developmental toxicity at 24 mg/kg/day based on decreased body weight and increased skeletal abnormalities observed at the 72 mg/kg/day dose level.

7. Imidacloprid, which was tested in a battery of 23 mutagenic assays, was negative for mutagenic effects in all but two of the assays. Imidacloprid tested positive for chromosome aberrations in an *in vitro* cytogenetic study with human lymphocytes for the detection of induced clastogenic effects, and for genotoxicity in an *in vitro* cytogenetic assay measuring sister chromatid exchange in Chinese hamster ovary cells.

Dietary risk assessments for imidacloprid indicate that there is minimal risk from established tolerances and the proposed tolerance for dried hops. A cancer risk assessment is not appropriate for imidacloprid since the pesticide is assigned to ''Group E'' (evidence of noncarcinogenicity for humans) of EPA's cancer classification system. Dietary risk assessments for the pesticide were conducted using the Reference Dose (RfD) to assess chronic exposure and risk and the Margin of Exposure (MOE) for acute toxicity.

The RfD is calculated at 0.057 mg/kg/of body weight/day based on a NOEL of 5.7 mg/kg/day from the 2-year rat feeding/carcinogenicity study and 100-fold uncertainty factor. The theoretical maximum residue contribution (TMRC) from existing tolerances and the proposed tolerance for dried hops utilizes less than 5 percent of the RfD for the general population and 26 percent of the RfD for nonnursing infants less than one year in age.

The MOE is a measure of how closely the high end acute dietary exposure comes to the no-observed-effect level from the toxicity endpoint of concern. For imidacloprid the MOE was calculated as a ratio of the NOEL (24 mg/kg/day) from the rabbit developmental toxicity study to dietary exposure, as estimated for the population subgroup at greatest risk (females of childbearing age). The MOE for this subgroup is estimated at 2500 for high-end exposure. Acute dietary margins of exposure of less than 100 are generally of concern to EPA. A MOE of 2,500 poses minimal risk.

Established tolerances for meat, milk, poultry, and eggs are adequate to cover secondary residues resulting from the feeding of spent hops to livestock.

The metabolism of imidacloprid in plants and animals is adequately understood. An adequate analytical method is available for enforcement purposes. The enforcement method 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 method is being made available in the interim to any one interest in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5937.

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 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

A record has been established for this rulemaking under docket number [PP 5E4425/P619] (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 p.m., Monday through Friday, excluding 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 (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