

(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 was negative for mutagenic effects in all but two of 23 mutagenic 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 cucurbit vegetables. A cancer risk assessment is not appropriate for imidacloprid since the pesticide is assigned to "Group E" (no evidence of carcinogenicity) 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.

The RfD is calculated at 0.057 mg/kg/day 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 utilizes less than 15 percent of the RfD for the general population and less than 30 percent of the RfD for nonnursing infants less than 1 year in age. The proposed tolerance for cucurbit vegetables would utilize less than 1 percent of the RfD for the general population and all population subgroups.

There is no reasonable expectation that secondary residues will occur in milk and eggs, or meat, fat, and meat byproducts of livestock or poultry; there are no livestock feed items associated with the cucurbit vegetables.

The metabolism of imidacloprid in plants and livestock is adequately

understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring.

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 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 5E4598/P638] (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, excluding legal holidays. The public record is located in Room 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 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.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator 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: November 30, 1995.

Stephen L. Johnson,  
Director, Registration Division, Office of  
Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.