file format or ASCII format. All comments and data in electronic form must be identified by the docket number [PP 3F4169 and FAP 3H5655/P628]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document. FOR FURTHER INFORMATION CONTACT: BV mail: Dennis H. Edwards, Jr., Product Manager (PM) 19, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6386; e-mail: edwards.dennis@epamail.epa.gov.

Comments and data will also be

accepted on disks in WordPerfect in 5.1

I. Introduction

SUPPLEMENTARY INFORMATION:

Pursuant to petitions from Miles, Inc., EPA issued final rules establishing pesticide tolerances under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, for residues of the insecticide (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2imidazolidinimine, in or on the raw agricultural commodities apples at 0.5 part per million (ppm), potatoes at 0.3 ppm, and cottonseed at 6.0 ppm. Based on a feed additive petition (FAP) 3H5655 from Miles, Inc., EPA established food or feed additive regulations under FFDCA section 409, 21 U.S.C. 348, for the combined residues of imidacloprid and its metabolites containing the 6chloropyridinyl moiety, all expressed as imidacloprid, on apple pomace (wet or dried) at 3 ppm, on potato chips at 0.4 ppm, on potato waste at 0.9 ppm, and on cottonseed meal at 9.0 ppm. The tolerances for cottonseed and cottonseed meal were established as time-limited tolerances and are due to expire on November 30, 1996 (see the Federal Register of November 30, 1994 (59 FR 61278)).

The reason the cottonseed and cottonseed meal tolerances were established as 2-year time-limited tolerances was to enable Bayer to complete additional cotton residue trials and present a final report. On June 2, 1994, the Agency issued a guidance document on crop residue trials. Among other things, this document provided guidance on the number and location of domestic crop field trials for establishment of pesticide residue trials.

Based on this guidance document, the Agency determined that additional residue trials were needed and residue data on gin trash were required to fully support the cotton tolerances.

On March 31, 1995, Bayer submitted the additional residue studies. A request was also submitted to establish a tolerance for cotton gin byproducts. These data have been reviewed and determined to be adequate to support both the proposed cotton gin byproducts tolerance and the removal of the expiration date for the cottonseed and cottonseed meal tolerances.

EPA, however, has determined a section 409 feed additive tolerance is no longer necessary to prevent cottonseed meal from being deemed adulterated, and, therfore, EPA is preparing to revoke the cottonseed meal tolerance. Additionally, EPA is proposing to establish a maximum residue limit for imidacloprid residues in cottonseed meal to simipifly enforcement.

II. Statutory Background

The FFDCA, 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as "tolerances." Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App. at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities and for residues on processed food. For pesticide residues in or on raw commodities, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408 of the act. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409 which pertains to "food additives." 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive tolerances. Section 409 food additive tolerances are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food will not render the food adulterated if the

residue results from application of the pesticide to a raw commodity consistent with a section 408 tolerance and the residue in the processed food when "ready to eat" has been removed to the extent possible by good manufacturing processes and is below the tolerance set under section 408. This exemption in section 402(a)(2) is commonly referred to as the "flow-through" provision because it allows the section 408 raw food tolerance to flow through to the processed food form.

III. Proposed Removal of Expiration Date from Cottonseed Tolerance and Establishment of Cotton Gin Byproduct Tolerance

The scientific data submitted in the petition and other relevant material have been evaluated regarding the Miles' request to remove the expiration date from the cottonseed tolerance and to establish a tolerance for cotton gin byproducts. The toxicological data considered in support of the tolerance include:

1. A three-generation rat reproduction study with a no-observed-effect level (NOEL) of 100 ppm (8 mg/kg/bwt); rat and rabbit teratology studies were negative at doses up to 30 mg/kg/ bwt and 24 mg/kg/bwt, respectively.

2. A 2-year rat feeding/carcinogenicity study that was negative for carcinogenic effects under the conditions of the study and had a NOEL of 100 ppm (5.7 mg/kg/bwt in male and 7.6 mg/kg/bwt female) for noncarcinogenic effects that included decreased body weight gain in females at 300 ppm and increased thyroid lesions in males at 300 ppm and females at 900 ppm.

3. A 1-year dog feeding study with a NOEL of 1,250 ppm (41/mg/kg/bwt).

4. A 2-year mouse carcinogenicity study that was negative for carcinogenic effects under conditions of the study and that had a NOEL of 1,000 ppm (208/mg/kg/day).

There is no cancer risk associated with exposure to this chemical. Imidacloprid has been classified under "Group E" (no evidence of carcinogenicity for humans) under EPA's cancer Assessment Guidelines by the Office of Pesticide Programs (OPP) Reference Dose (RFD) Committee.

The reference dose (RfD), based on the 2-year rat feeding/ carcinogenic study with a NOEL of 5.7 mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. The theoretical maximum residue contribution (TMRC) from published uses is 0.008088 mg/kg/day. This represents 14% of the RfD for the overall U.S. population. For exposure of the most highly exposured subgroup in the population, children