

(ages 1 to 6 years), the TMRC is 0.016735 mg/kg/day. This is equal to 30% of RfD. The proposed cotton gin byproduct tolerance will not increase the TMRC. Dietary exposure from the existing uses and proposed uses will not exceed the reference dose for any subpopulation (including infants and children) based on the information available from EPA's Dietary Risk Evaluation System.

The nature of the residue in plants and livestock is adequately understood. The residues of concern are imidacloprid and its metabolites that contain the 6-chloropyridinyl moiety, all calculated as imidacloprid. The analytical methods are common moiety methods for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring. Adequate geographically representative magnitude of the residue crop field trial data for imidacloprid on cotton indicate that residues of total imidacloprid will not exceed the proposed tolerances when the formulation is used as directed. Based on the results of the imidacloprid bovine and poultry feeding studies, finite imidacloprid residues will occur in meat, milk, poultry, and eggs from feeding of imidacloprid-treated feed items, or their processed feed items, when the formulations are used as directed. Appropriate secondary tolerances are established.

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

This pesticide is considered useful for the purposes for which the tolerances are sought. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerances be established as set forth below.

#### IV. Proposed Revocation of the Feed Additive Tolerance for Cottonseed Meal

In June 1995 (60 FR 31300, June 14, 1995), EPA issued a revised policy concerning when section 409 food and feed additive tolerances were needed to prevent the adulteration of foods and animal feeds. Under EPA's revised policy, a section 409 tolerance is necessary for pesticide residues in processed food when it is likely that the level of some residues of the pesticide will exceed the section 408 tolerance level in "ready to eat" processed food. Of particular relevance to the imidacloprid feed additive tolerance is

EPA's decision to interpret the term "ready to eat" processed food as food ready for consumption "as is" without further preparation. For foods that are found to be not "ready to eat," EPA takes into account the dilution of residues that occurs in preparing a "ready to eat" food.

EPA has determined that cottonseed meal is not a "ready to eat" animal feed. EPA has found no evidence that cottonseed meal is fed to livestock as a stand-alone feedstock. Rather, cottonseed meal is used as an ingredient in animal feeds. As such, cottonseed meal can constitute up to 50 percent of an animal feed.

The section 408 tolerance for imidacloprid on cottonseed is 6 parts per million (ppm). The highest residue found in crop field trials for imidacloprid on cotton was 5.2 ppm. A processing study showed that in producing cottonseed meal residues concentrated 50 percent (a concentration factor of 1.5X). Thus, given this information, it is likely that imidacloprid residues of 7.8 ppm (1.5 X 5.2) could occur in cottonseed meal. However, to project what residues are likely in "ready to eat" animal feed containing cottonseed meal the 7.8 ppm level must be divided by 2 to allow for dilution occurring when cottonseed meal is added to other ingredients in the preparation of animal feed. Once this dilution is taken into account, the likely residue of imidacloprid in animal feed would not be expected to exceed 3.9 ppm. Since this is below the section 408 tolerance level, animal feed containing such residue levels would not be adulterated, and no section 409 tolerance is needed. Accordingly, EPA proposes to revoke the section 409 feed additive tolerance for imidacloprid in cottonseed meal.

#### V. Proposed Establishment of a Maximum Residue Level of Imidacloprid Residues in Cottonseed Meal

In the June 1995 policy announcement, EPA noted that it generally would establish maximum residue levels (MRLs) under FFDCA section 701 for not-ready-to-eat foods where such foods could contain residues exceeding the section 408 tolerance. EPA's rationale was that such MRLs are important to the efficient enforcement of the FFDCA. It is far less resource intensive for FDA and USDA, which are the Federal agencies which regulate pesticide residue levels in foods, to monitor residue levels in the bulk commodities used in preparing ready-to-eat foods than in the myriad of

ready-to-eat foods manufactured from such commodities.

MRLs will enforce the statutory requirements that, where no food additive tolerance has been established, pesticide residues in processed food resulting from application of the pesticide to the precursor raw commodity render the food adulterated unless the pesticide was used in conformity with the applicable section 408 tolerance and the pesticide residue has been removed to the extent possible in good manufacturing practice. 21 U.S.C. 342(a)(2)(C). Thus, MRLs will reflect the maximum residue in processed food consistent with a legal level of residues being present on the precursor raw commodity and the use of good manufacturing practices.

Processed foods not in compliance with an applicable MRL will be deemed adulterated under section 402 of the act.

EPA will compute the MRL by multiplying the maximum residue found in the raw commodity in field trials by the concentration factor determined in processing studies using good manufacturing practices. As noted, the maximum residue from the imidacloprid field trials is 5.2 ppm and the concentration factor for processing is 1.5X. Multiplying 5.2 ppm by 1.5 yields a product of 7.8 ppm. EPA believes it is appropriate to round 7.8 ppm up to 8 ppm and proposes 8 ppm as the MRL for imidacloprid residues in cottonseed meal. For purposes of enforcement of the MRL, the same analytical method used for enforcement of the section 408 tolerances should be used.

EPA is proposing to place this MRL in existing part 186 of title 40 of the Code of Federal Regulations rather than creating a new part of title 40. Currently, 40 CFR part 186 contains section 409 feed additive tolerances organized by pesticide. EPA believes it will be clearer to the regulated community and to enforcement personnel if all regulations pertaining to residue levels of a pesticide in animal feeds are located in the same part of the Code of Federal Regulations. Because EPA is proposing to expand the type of regulation that would be included in part 186, EPA proposes modifying the title of part 186 to "Pesticides in Animal Feeds" to reflect that change.

#### VI. Public Participation

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