

and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, in or on fruiting vegetables, leafy vegetables, head and stem brassica vegetables, cotton, cucurbits, grapes, and potato. The tolerances are set at the following value: Fruiting vegetables, 0.7 part per million (ppm); leafy vegetables, 5.0 ppm; tomato paste, 1.0 ppm; cucurbits, 0.5 ppm; head and stem brassica vegetables, 1.4 ppm; grape, 0.8 ppm; raisin, 2.5 ppm; potato, 0.05 ppm; chips, 0.10 ppm; granules, 0.15 ppm; cotton seed undelinted at 0.2 ppm, and cotton gin byproducts at 7.0 ppm. Tolerances for meat, milk, and byproducts is set at 0.05 ppm. This new active ingredient has been accepted by EPA as a reduced risk chemical. EPA has determined that the petitions contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

#### A. Residue Chemistry

1. *Plant metabolism.* The primary metabolic pathways of dinotefuran in plants (rice, apple, potato, oilseed, rape, and lettuce) were similar to those described for animals, with certain extensions of the pathway in plants. Parent compound, dinotefuran, and two metabolites, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea were major metabolites in all crops. The metabolism of dinotefuran in plants and animals is understood for the purposes of the proposed tolerances. Parent dinotefuran and the metabolites, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea are the residues of concern for tolerance setting purposes.

2. *Analytical method.* Mitsui Chemicals, Inc., has submitted practical analytical methodology for detecting and measuring levels of dinotefuran and its metabolites, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, in or on raw agricultural commodities (RACs). The high performance liquid chromatography (HPLC) method was validated for determination of, dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea in or on tomatoes, peppers, cucurbits, brassica, grapes, potatoes, and lettuce for raw agricultural commodity matrices and in or on tomato paste, puree, grape juice, raisins, potato chips, granules, and wet

peel for processed commodity matrices. After extraction with a water/acetonitrile mixture and clean up with hexane and extraction columns, concentrations of dinotefuran and its metabolites were quantified after HPLC separation by mass spectrometry/molecular size (MS/MS) detection. The limit of quantitation (LOQ) was 0.01 ppm for all matrices.

The HPLC method was validated for the determination of dinotefuran and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea in or on cotton (undelinted seed, gin trash, meal, hulls, refined oil), and leafy vegetables. After extraction with a water/acetonitrile mixture and clean up dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea were quantified after HPLC separation by MS/MS detection. For undelinted seed, gin trash, meal, and hulls, a LOQ of 0.05 milligram/kilogram (mg/kg) and a working range from 0.05 to 0.50 mg/kg were successfully validated for dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea. For refined oil, a LOQ of 0.01 mg/kg and a working range from 0.01 to 0.10 mg/kg were successfully validated for dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea. An HPLC method was validated for the determination of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea in lettuce. After extraction with water/acetonitrile mixture and clean-up, dinotefuran was quantified after HPLC separation by ultraviolet ray (UV) detection, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea by MSD. A LOQ 0.010 mg/kg and a working range from 0.01 to 5.00 mg/kg were successfully validated from dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea. All of the above methods have been independently validated.

3. *Magnitude of residues.* Crops in residue trials were treated at maximum label rates and harvested at the specified minimum treatment to harvest intervals. The residue method for dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, in all components utilized HPLC separation with MS/MS detection.

For cucurbit vegetables (crop group 9), residue trials were conducted for each of the three representative crops, cucumbers, melons, and squash. The

proposed tolerance in or on cucurbit vegetables for combined residues of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, is 0.5 ppm. The maximum combined residue found for the representative cucurbit vegetable crops was 0.44 ppm for a melon sample.

For leafy vegetables (crop group 4), residue trials were conducted for each of the four representative crops, celery, leaf lettuce, head lettuce, and spinach, at six locations. The proposed tolerance in or on leafy vegetables for combined residues of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, is 5.0 ppm. The maximum combined residue found for the representative leafy vegetable crops was 4.36 ppm for a spinach sample.

Residue trials for cotton were conducted at 13 locations and undelinted cotton seed samples were collected and analyzed. Cotton gin byproducts (gin trash) samples were obtained for 7 of the locations. Processing studies with analyses of cotton seed meal, hulls, and oil were performed with cotton seed harvested at two locations that were both treated with 5X the maximum label rate. The proposed tolerance for combined residues of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, in or on cotton seed undelinted is 0.2 ppm. All cotton seed residue samples had combined residues of less than 0.2 ppm. The proposed tolerance for cotton gin byproducts is 7.0 ppm for combined residues of dinotefuran and its two major metabolites. The maximum combined residues for cotton gin byproducts in these trials was 6.4 ppm. Processing studies established that residues of dinotefuran and its metabolites, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, did not concentrate in cotton seed meal, oil, or hulls. Therefore, tolerances are not proposed for these processing fractions.

Residue trials for grapes were conducted at 13 locations and 2 grape juice and raisin processing studies were performed with grapes from exaggerated treatment rate applications. The proposed tolerance for combined residues of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, in or on grapes is 0.8 ppm. The maximum combined residue for an individual grape residue sample was 0.73 ppm and the highest average field trial (HAFT) for grapes had