

agricultural commodity (RAC) grain sample or in sugarcane. The residue of concern in grain and sugarcane is best defined as the parent, flufenpyr-ethyl. However, consistent with plant metabolism studies, finite residues of *S*-3153-acid-4-*OH* were detected in field corn forage and stover, and tolerances are proposed.

2. *Ruminant and poultry metabolism.* Metabolism studies in goats and hens demonstrated that transfer of administered ^{14}C -flufenpyr-ethyl residues to tissues was low. Total ^{14}C -residues in goat milk, muscle and tissues accounted for less than 1% of the administered dose. Total radiocarbon residues (parent equivalent) were less than 0.01 ppm in all cases except for approximately 0.15 ppm in kidney and 0.04 ppm in liver. Residues were identified in excreta and all appropriate tissues. In milk (0.002 to 0.008 ppm), kidney, and liver approximately 70 to 90 percent of the residues was identified as the ester hydrolysis product, *S*-3153-acid. In poultry, total ^{14}C residues (parent equivalent) in eggs, muscle and tissues accounted for about 0.1% of the administered dose, and were less than 0.01 ppm in all cases except for approximately 0.02 ppm in liver. More than half of the liver residue was *S*-3153-acid.

3. *Analytical method.* Practical analytical method for detecting and measuring levels of flufenpyr-ethyl and validated in/on all appropriate agricultural commodities and respective processing fractions. Methodology that converts the *S*-3153-acid-4-*O*-glucoside to the corresponding aglycone, *S*-3153-acid-4-*OH*, was developed and validated with an LOQ of 0.02 ppm. The extraction methodologies have been validated using plant samples containing aged radiochemical residue samples from ^{14}C -metabolism studies. The methods have been validated in soybean seed, corn grain, and corn stover at an independent laboratory. The LOQ for flufenpyr-ethyl is 0.01 ppm and the LOQ for *S*-3153-acid-4-*OH* is 0.02 ppm which will allow monitoring of food with residues at the levels proposed for the tolerances. Both flufenpyr-ethyl and *S*-3153-acid-4-*OH* have been evaluated using the FDA multiresidue method protocol.

4. *Magnitude of residues—i. Soybean seed.* Twenty-two field trials in soybeans were conducted in 1997 and 1998 in 15 states representing approximately 99% of the soybean acreage in the U.S. (EPA Regions II, IV, and V). Analysis of duplicate samples from these trials showed that at the proposed maximum application rate

(24.5 grams active ingredient (a.i.)/acre), or at 5 times the proposed maximum application rate, there were no measurable residues of flufenpyr-ethyl in soybean seed (<0.005 ppm). The analytical LOQ was 0.01 ppm. A processing study in soybean seed treated at the 5-fold application rate demonstrated that flufenpyr-ethyl was undetectable in all processed commodities. All these data support a proposed tolerance of 0.01 ppm for flufenpyr-ethyl in/on soybean seed. No additional tolerances are necessary for processed commodities.

ii. *Sugarcane cane.* Nine field trials in sugarcane were conducted in 1998 in 4 states representing approximately 100% of the sugarcane acreage in the U.S. (EPA Regions II, IV and V). Analysis of duplicate samples from these trials showed that at the proposed seasonal maximum application rate (24.5 grams a.i./acre), or at five times the proposed maximum application rate, there were no measurable residues of flufenpyr-ethyl in sugarcane cane (<0.005 ppm). The analytical LOQ was 0.01 ppm. Because sugarcane is the vegetative portion of the plant, it is possible that residues of the carboxylic acid phenol metabolite (*S*-3153-acid-4-*OH*) might be present. With an LOQ of 0.02 ppm, there was no detected metabolite in any sugarcane sample. Samples of processed commodities from the sugarcane processing studies treated at 5-fold were not analyzed because of the absence of finite residues in any of the cane RAC samples. All these data support a proposed tolerance of 0.01 ppm for flufenpyr-ethyl in/on sugarcane cane. No additional tolerances are necessary for processed commodities.

5. *Field corn.* Twenty-four field trials in field corn were conducted in 1997 (10) and 1998 (14) in 16 states representing approximately 97% of the field corn acreage in the U.S. (EPA Regions I, II, V, VI, VII, VIII, and X). Field plots were treated at the V10 crop stage. Forage was sampled 32 to 65 days after treatment at late R4 to early R5 crop stage. Grain and stover were sampled at dry maturity 58 to 115 days after application.

i. *Field corn grain.* Analysis of duplicate samples of grain from these trials showed that at the proposed maximum application rate (24.5 grams a.i./acre), at half the proposed maximum application rate (12 grams a.i./acre), or from two field plots treated at five times the proposed maximum application rate (121 grams a.i./acre) there were no measurable residues of flufenpyr-ethyl (<0.005 ppm). The analytical LOQ was 0.01 ppm. A processing study in field corn grain treated at the five times the

normal application rate demonstrated that flufenpyr-ethyl was undetectable in all processed commodities. All these data support a proposed tolerance of 0.01 ppm for flufenpyr-ethyl in/on field corn grain. No additional tolerances are necessary for processed commodities.

ii. *Field corn forage and stover.* Analysis of duplicate samples of forage and stover from these trials showed that at the proposed maximum application rate (24.5 grams a.i./acre), and at half the proposed maximum application rate (12 grams a.i./acre) there were no measurable residues of flufenpyr-ethyl (<0.005 ppm). In forage and stover from plots treated at 5 times the proposed application rate (121 grams a.i./acre) finite residue of flufenpyr-ethyl were detected (0.015 to 0.008 ppm). Forage and stover samples were also analyzed for *S*-3153-acid-4-*OH*. Finite residues of the metabolite were detected in 28 of 52 forage samples, and 11 of 54 stover samples from plots treated at 24.5 grams a.i./acre. Maximum residue values in the two feed commodities were 0.03 ppm. Forage and stover samples from the two plots treated at the 5-fold rate showed maximum residue values of 0.05 ppm. All these data support proposed tolerances of 0.01 ppm for flufenpyr-ethyl and 0.04 ppm *S*-3153-acid-4-*OH* in/on field corn forage and stover.

6. *Secondary residues.* Using proposed tolerances, or for field corn forage and stover the sum of the tolerances for parent and metabolite, to calculate the maximum feed exposure to fed animals, and using the very low potential for residue transfer demonstrated in the lactating goat and laying hen metabolism studies, detectable secondary residues in animal tissues, milk, and eggs are not expected. Therefore, tolerances are not proposed for these commodities.

7. *Rotational crops.* The results of a confined rotational crops accumulation study with ^{14}C -flufenpyr-ethyl indicate that no rotational crop planting restrictions or rotational crop tolerances are required.

B. Toxicological Profile

A full battery of toxicology testing including studies of acute, chronic, oncogenicity, developmental, mutagenicity, and reproductive effects is available for flufenpyr-ethyl. The acute toxicity of flufenpyr-ethyl is low by all routes. Subchronic and chronic toxicity studies exhibit no observable adverse effect level (NOAEL) values from a low of 40 milligrams/kilogram/day (mg/kg/day) (male mouse 18-month oncogenicity) to greater than 1,000 mg/kg/day. Flufenpyr-ethyl is not oncogenic