

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

Codex and Mexico do not have maximum residue limits (MRLs) for glufosinate ammonium and its metabolites for the proposed crops or livestock commodities. Canada does not have MRLs for glufosinate ammonium and its metabolites for the proposed crops, poultry commodities or milk, but does have a MRL of 1 ppm for ruminant liver and kidney.

V. Conclusion

Therefore, the tolerance is established for combined residues of glufosinate ammonium and its metabolites in or on bushberry subgroup, Lingonberry, junberry and salal at 0.15 ppm, cattle, fat at 0.40 ppm, cattle, meat at 0.15 ppm, cattle, meat byproducts at 6.0 ppm, cotton, gin byproducts at 15 ppm, cotton, undelinted seed at 4.0 ppm, egg at 0.15 ppm, goat, fat at 0.40 ppm, goat, meat at 0.15 ppm, goat, meat byproducts at 6.0 ppm, hog, fat at 0.40 ppm, hog, meat at 0.15 ppm, hog, meat byproducts at 6.0 ppm, horse, fat at 0.40 ppm, horse, meat at 0.15 ppm, horse, meat byproducts 6.0 ppm, Milk at 0.15 ppm, poultry, fat at 0.15 ppm, poultry, meat at 0.15 ppm, poultry, meat byproducts 0.60 ppm, sheep, fat at 0.40 ppm, sheep, meat at 0.15 ppm, and sheep, meat byproducts 6.0 ppm, cotton, gin byproducts at 15 ppm, rice, grain at 1.0 ppm, rice, straw at 2.0 ppm, and rice, hull at 2.0 ppm.

VI. Response to Comments

The overall thrust of the comments from the Sierra Club was that “large quantities of glufosinate ammonium herbicide will be utilized on transgenic rice crops in the United States and abroad . . . even though the herbicide may have side effects on humans, farm animals and beneficial insects.” The testing of pesticides will often reveal that a pesticide has the potential to create adverse effects in animals and/or insects; those risks are addressed via registration under FIFRA. The critical issue addressed by FFDCA is whether there is an adequate margin of safety between the aggregate exposure level of

humans to the pesticide and the level that potentially may be harmful. As EPA described in Unit III.E. above, EPA’s risk assessment showed that an adequate margin was available for EPA to conclude that there is a reasonable certainty of no harm for the general population including infants and children.

EPA has reprinted each of Sierra Club’s more specific comments below and responded to each individually.

1. *Comment—plant metabolism of glufosinate.* A concern is other plant metabolites of glufosinate ammonium may occur in addition to the two primary metabolites identified in the grain and straw, since the two substances did not appear to account for 100% of the total radioactive residues in the two plant tissues tested. While more than 80% appeared to be accounted for, Aventis needs to identify whether additional metabolites were produced. The two primary metabolites identified as being typical of plant metabolism in the grain at harvest were 3-methylphosphinicopropionic acid, being—70% of the total radioactive residues (TRR). Another residue in the grain was *N*-acetyl-L-glufosinate (2-acetamido-4-methylphosphinobutanoic acid), at about 11% of the TRR and parent at 5–6% of the TRR. In the straw, 3-methylphosphinicopropionic acid was the major metabolite comprising approximately 60% of the TRR. Lesser amounts of the parent (about 17% of the TRR) and *N*-acetylglufosinate (10–13% of TRR) were found in the straw fraction.

Agency response. The transgenic rice metabolism study was conducted according to the regulatory guideline requirements (OPPTS 860.1500) and conformed to EPA Good Laboratory Practice (GLP) Standards (the % TRR figures given below are averages of four samples). The study indicated that glufosinate ammonium, *N*-acetylglufosinate, and 3-MP accounted for 88% and 91% of the total radioactive residue (TRR) found in rice grain and rice straw, respectively (grain and straw are the only rice raw agricultural commodities (RACs)). The remainder of the radioactivity was identified as 2-methylphosphinico-acetic acid (grain—1% TRR; straw—2% TRR), several unknowns when combined accounted for 2% TRR (rice grain) and 3% TRR (rice straw), and fiber bound residues (grain—8% TRR; straw—5% TRR). The petitioner identified/characterized 99% and 101% of the TRR in rice grain and rice straw, respectively. In previously submitted transgenic canola and non-transgenic apple, corn, lettuce,

soybeans, and wheat metabolism studies, the petitioner demonstrated the incorporation of radioactivity into nature plant constituents. On the basis of the transgenic rice metabolism study and the previously submitted metabolism studies, EPA concluded that the residue identification/characterization procedures performed were adequate and the residues of concern in transgenic rice, for purposes of tolerance enforcement and risk assessment, are glufosinate ammonium, *N*-acetylglufosinate, and 3-methylphosphinico-propionic acid (3-MP).

2. *Comment—analytical method.* We ask EPA if any independent sampling and gas chromatography analyses were conducted besides that performed by Aventis and its contractors. We request that an independent sampling and G.C. analysis program be carried out if Aventis has not had a third party independent contractor, since we are skeptical of Aventis’ sampling data and analyses. We generally agree that the enforcement analytical method of utilizing gas chromatography appears to be acceptable for detecting and measuring levels of glufosinate ammonium and metabolites with a general limit of quantification of 0.05 ppm to allow detection of glufosinate residues at or above the proposed tolerances. We wonder if glufosinate residues might have been found between 0.01 ppm and 0.05 ppm, and that due to its toxicity, EPA should have required a lower detectability limit be utilized to demonstrate if glufosinate residues were missed below 0.05 ppm or 50 parts per billion (ppb) concentration down to 1 ppb.

Agency response. The rice magnitude of the residue study was conducted according to the regulatory guideline requirements (OPPTS 860.1500) and conformed to EPA GLP Standards. The rice grain and straw samples were analyzed using a method similar to that previously validated by an independent laboratory and by the EPA. Based on these validation procedures and the validation and concurrent recovery data submitted with the transgenic rice field trials, EPA concluded that the method was appropriate for data collection purposes.

EPA understands that residues below the level of quantification (< LOQ) does not mean that residues are not present. The dietary analyses assumed average field trial residues for rice commodities. When calculating the average, half LOQ residues were assumed for residues < LOQ. Therefore, the dietary risk assessment took into account the possibility of residues between 0.01 and