

Safety Assessment of Roundup Ready® Corn Event GA21

Executive Summary

Glyphosate, the active ingredient in Roundup® agricultural herbicides, kills plants by inhibiting the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). This enzyme is a critical step in the shikimic acid pathway for the biosynthesis of aromatic amino acids in plants and microorganisms, and its inhibition leads to the lack of growth in plants. The aromatic amino acid biosynthetic pathway is not present in mammalian, avian or aquatic animals. This explains the selective activity in plants and contributes to the low risk to human health and the environment from the use of glyphosate according to label directions.

Roundup Ready® corn event GA21 contains a modified *epsps* gene from corn (*Zea mays*, L.). The modified maize EPSPS (mEPSPS) protein differs from wild-type maize EPSPS by two amino acids. This results in an EPSPS protein with greater than 99.3% sequence identity to that produced naturally in corn. The mEPSPS protein has a low affinity for glyphosate compared to the wild-type EPSPS enzyme. Thus, when corn plants expressing the mEPSPS protein are treated with glyphosate, the plants are unaffected. The continued action of the tolerant mEPSPS enzyme provides the plant's need for aromatic acids.

The Roundup Ready corn plant was made using particle acceleration technology with a linear DNA fragment of a plasmid carrying the *mepsps* gene.

The food and feed safety of Roundup Ready corn was established based upon: the evaluation of mEPSPS activity and homology to EPSPS proteins present in a diversity of plants, including those used for foods; the low dietary exposure to mEPSPS, the rapid digestibility of mEPSPS, and the lack of toxicity or allergenicity of EPSPSs generally and by direct studies of this specific mEPSPS. The nutritional and compositional equivalence of Roundup Ready corn to conventional corn was demonstrated by analyses of key nutrients including protein, fat, carbohydrates, moisture, calories, amino acids, fatty acids, and minerals. Nutritional equivalence of Roundup Ready corn to conventional corn was confirmed by evaluation in the performance of broiler chickens. The environmental impact of Roundup Ready corn is the same as that of conventional corn. Glyphosate-tolerant volunteer corn is infrequent and easily managed in the farmer's field. The results of all these studies demonstrate that Roundup Ready corn is equivalent to traditional corn with respect to food, feed and environmental safety.

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