Safety Assessment of Roundup Ready® Soybean Event 40-3-2

Executive Summary

Using modern biotechnology, Monsanto Company has developed Roundup Ready® soybean varieties that confer tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides, by the production of the naturally occurring glyphosate-tolerant CP4 enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein. The EPSPS enzyme is present in the shikimic acid pathway for the biosynthesis of aromatic amino acids in plants and microorganisms. Inhibition of this enzyme by glyphosate leads to a deficiency in the production of aromatic amino acids and 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 soybean event 40-3-2 was produced by introduction of the glyphosate-tolerant *cp4 epsps* coding sequence derived from the common soil bacterium *Agrobacterium sp*. strain *CP4* into the soybean genome using particle-acceleration transformation. The CP4 EPSPS protein is a member of the class of EPSPS proteins found ubiquitously in plants and microorganisms.

The tolerance of Roundup Ready soybeans to glyphosate has been demonstrated since 1991 in field trials conducted throughout the United States and since 1996 with commercial production in the United States, Canada and Argentina. Roundup Ready soybeans were planted in 1996 on less than 5% of the U.S. soybean acres. In the 2001 growing season, 71% of the soybeans -- approximately 54 million acres of the 75.4 million acres of the soybeans grown in the U.S. -- were Roundup Ready soybeans. In Argentina, where the adoption rate is estimated to be greater than 95%, Roundup Ready soybeans were grown on over 25 million acres in 2001. Globally, Roundup Ready soybeans made up 63% of all transgenic crops grown in 2001. One of the reasons growers have rapidly adopted the Roundup Ready soybean is the simplicity it offers in weed control. Since Roundup agricultural herbicides are highly effective against the vast majority of annual and perennial grasses and broadleaf weeds, growers planting Roundup Ready soybeans are able to reduce the number of herbicides used to control the economically destructive weeds that grow in their fields and thereby realize a savings in weed control costs. This reduction in herbicide use has benefited the environment by reducing the number of herbicide applications and also allows growers to implement integrated weed management practices in their fields – practices that are generally not possible when pre-plant or pre-emergent herbicides are used.

The food, feed and environmental safety of Roundup Ready soybean was established based upon: the evaluation of the functional and structural similarity of the CP4 EPSPS protein to a diverse family of EPSPS proteins typically present in food and feed derived from traditional plant and microbial sources; the low dietary exposure to the CP4 EPSPS protein; the lack

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toxicity or allergenicity of EPSPS proteins in general; and by direct safety studies of the CP4 EPSPS protein. Furthermore, the nutritional equivalence and wholesomeness of Roundup Ready soybeans compared to conventional soybeans was demonstrated by the analysis of key nutrients, including proximates, amino acid and fatty acid composition, as well as anti-nutrients. The nutritional equivalence of Roundup Ready soybeans to conventional soybeans was confirmed in numerous feeding studies with rats, cows, pigs, broiler chickens, fish and quail. The environmental impact of Roundup Ready soybeans is also comparable to conventional soybeans. The results of these studies demonstrate that Roundup Ready soybeans are as safe as conventional soybeans with respect to food, feed and environmental safety.