Safety Assessment of Roundup Ready[®] Cotton Event 1445

Executive Summary

Using modern biotechnology, Monsanto Company has developed Roundup Ready[®] cotton plants that confer tolerance to glyphosate, the active ingredient in Roundup agricultural herbicides, by the production of the CP4 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein. Three genes were introduced into the cotton genome to produce this product: the *cp4 epsps* gene derived from the common soil bacterium *Agrobacterium* sp. strain *CP4* which encodes the naturally glyphosate-tolerant EPSPS protein, the target site for glyphosate action; the *neomycin phosphotransferase II (nptII)* gene which provides a plant selectable marker; and the *3"(9)-O-aminoglycoside adenylyltransferase (aad)* gene, a bacterial selectable marker. The *cp4 epsps* and *nptII* genes are expressed in the plants; the *aad* gene-product is not produced in the plants as this gene is under the control of a bacterial promoter.

Results from field experiments conducted in 1992, 1993 and 1994 at over 65 locations throughout the United States and commercial production of Roundup Ready cotton for four years on six million acres in United States alone, have demonstrated that cotton containing the Roundup Ready gene is tolerant to topical applications of glyphosate up to the four-leaf stage of growth. Glyphosate, the active ingredient in Roundup agricultural herbicides, has been shown to be highly effective in controlling the majority of annual and perennial grasses and broad-leafed weeds. Growers planting Roundup Ready cotton are able to reduce the number of herbicides used to control the economically destructive weeds that grow in their fields (Culpepper and York, 1998).

The following summary provides information on the methods used to develop Roundup Ready cotton, the proteins produced, as well as an overview of the food, feed and environmental safety studies that have been conducted on Roundup Ready cotton. This summary includes: molecular characterization of the DNA inserted into Roundup Ready cotton, an assessment of the safety of the produced proteins, compositional analyses of the food and feed components to evaluate substantial equivalence to conventional cotton varieties, and an assessment of the environmental safety of this product.

These studies demonstrate the food, feed and environmental safety of Roundup Ready cotton by establishing the safety of the CP4 EPSPS and NPTII proteins to humans, animals and other non-target organisms; establishing the nutritional equivalence and wholesomeness of Roundup Ready cottonseed compared to cottonseed from conventional varieties; and confirming the lack of a negative impact of Roundup Ready cotton on the environment.

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