Safety Assessment of Roundup Ready Alfalfa Events J101 and J163

Executive Summary

Monsanto Company and Forage Genetics International have developed varieties of Roundup Ready® alfalfa that are tolerant to glyphosate, the active ingredient in Roundup® agricultural herbicides. Roundup Ready alfalfa commercialized varieties use a combination of two independent events: (J101 and J163)[1] combined (J101 × J163) through a conventional breeding process. Roundup Ready alfalfa was developed using *Agrobacterium*-mediated transformation to stably incorporate into the alfalfa genome a coding sequence (gene) producing a glyphosate-tolerant form of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). This protein is similar to naturally occurring EPSPS proteins found in other food crops, food processing aids like bakers yeast, and is the same as that found in other Roundup Ready crops on the market. This glyphosate-tolerant EPSPS was originally identified in the soil microorganism, *Agrobacterium* sp. strain CP4, and is designated CP4 EPSPS. The production of the CP4 EPSPS protein in plant tissues is the basis of the Roundup Ready trait in alfalfa varieties which contain events J101 and J163. Use of the Roundup Ready alfalfa system -- planting Roundup Ready alfalfa and subsequent application of a Roundup agricultural herbicide -- has the potential to offer significant agronomic and environmental benefits.

Alfalfa is a major forage (feed) crop in the U.S. and has been grown on over 20 million acres annually since the 1950s. Roundup Ready alfalfa was deregulated by USDA in June 2005. Available seed was planted in the US in 2005, with all products limited for domestic use. Roundup Ready alfalfa varieties enable growers to apply labeled Roundup agricultural herbicides from planting through five days before cutting, providing growers an additional tool for improved weed control, excellent crop safety and preservation of yield potential and quality. Since Roundup agricultural herbicides are highly effective against the vast majority of annual and perennial grasses and broadleaf weeds, alfalfa growers who use herbicides to control weeds will be able to reduce the number of herbicides used to control the economically destructive weeds that grow in their fields and thereby realize savings in weed control costs.

Roundup Ready alfalfa was developed for animal feed uses. However, there are minor food uses of alfalfa such as alfalfa sprouts and human consumption as dietary supplements; therefore, the safety assessment considered both food and feed uses of alfalfa. The feed and food safety assessment of Roundup Ready alfalfa utilized information on the safety and characterization of the introduced trait, the history of alfalfa as a safe feed and food source, and analyses which compared the composition of alfalfa varieties containing events J101 and J163 to control and conventional alfalfa varieties. Information and data on the introduced trait indicate that the CP4 EPSPS protein is safe

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[1] In accordance with OECD's "Guidance for the Designation of a Unique Identifier for Transgenic Plants," J101 has been assigned the unique identifier MON-00101-8, and J163 has been assigned the unique identifier MON-00163-7.

for consumption. The levels of key nutrients and components in Roundup ready alfalfa forage are comparable to the control and within the population of commercially available alfalfa varieties. As a result, forage from Roundup Ready alfalfa is substantially equivalent to forage of commercial varieties of alfalfa currently marketed. Collectively, these results establish that Roundup Ready alfalfa is safe for use as feed or food.

The environmental safety assessment of Roundup Ready alfalfa considered the biology and growth habits of alfalfa and determined whether the trait, the transformation and regeneration process impacted the pest or weediness potential of Roundup Ready alfalfa relative to the characteristics of the control or conventional alfalfa varieties. There were no biologically meaningful phenotypic (growth or development) differences between Roundup Ready alfalfa J101 and J163 populations and the alfalfa control or conventional reference varieties. Thus, there is no increased pest potential of Roundup Ready alfalfa populations. Other than the intentional change caused by the trait, the phenotype of alfalfa has not been changed as a result of the trait or transformation process. Based on these assessments, it was concluded that there were no unique environmental risks associated with the introduction of Roundup Ready alfalfa.

These studies establish the feed, food and environmental safety of Roundup Ready alfalfa. The feeds and foods derived from Roundup Ready alfalfa varieties are as safe and nutritious as current commercial varieties of alfalfa and the comparable feeds and foods derived from them. Introduction of Roundup Ready alfalfa varieties presents no unique risks to the environment beyond that due to use of conventional alfalfa varieties. This information has been independently reviewed by regulatory agencies in alfalfa production and in alfalfa importing countries, including reviews for environmental safety by the U.S. Department of Agriculture (http://www.aphis.usda.gov/brs/not_reg.html) and for feed and food safety by the U.S. Food and Drug Administration (http://www.cfsan.fda.gov/~lrd/biocon.html). Their reviews confirm the feed, food and environmental safety of Roundup Ready alfalfa.