

Regulatory Assessment of Roundup Ready® Alfalfa

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Roundup Ready® technology for improved weed control in alfalfa is being co-developed by Forage Genetics International (FGI) and Monsanto. The Roundup Ready gene, sourced from a soil bacterium and introduced into alfalfa, imparts tolerance to the broad-spectrum herbicide glyphosate, the active ingredient in Roundup® agricultural herbicides. The same gene and trait are now widely used in soy, maize, canola and cotton throughout the world. Roundup Ready alfalfa plants were produced at Montana State University in 1997 using an *Agrobacterium*-based plant transformation system. The subsequent distribution and testing of the transformed alfalfa plants has been strictly regulated by the U.S. Department of Agriculture-Animal and Plant Health Inspection Service-Biotechnology Regulatory Service (USDA-APHIS-BRS). In the U.S. and other nations that regulate genetically engineered plants, a thorough safety assessment must be conducted by the developer and approved by the government prior to unrestricted planting or first commercial use. The regulatory framework and safety assessment requirements differ among nations and they continue to evolve as new types and uses of biotechnology emerge. The result is that biotechnology-derived plants are rigorously scrutinized to thoroughly assess any possible impact on the environment or health. Monsanto and FGI have developed a regulatory strategy that respects major U.S. alfalfa domestic and export markets. In addition to full U.S. deregulation, regulatory approvals will be sought in the alfalfa-importing countries including Japan, Canada and Mexico. Safety assessments for Roundup Ready alfalfa were conducted to address food and feed safety and environmental impact.

Food and feed safety assessment involved an extensive battery of tests to both fully characterize the inserted gene and gene product. Characterizations included *cp4-epsps* gene insert integrity and stability; CP4-EPSPS protein expression levels and stability; and, the equivalence of the CP4-EPSPS protein expressed in alfalfa to the same CP4-EPSPS that has a history of safe use in other commercial crops. Compositional equivalence to conventional alfalfa varieties was demonstrated (greater than 35 key nutrients and anti-nutrients were measured).

The environmental assessment involved extensive vegetative and reproductive phenotypic studies. The relevance of Roundup Ready alfalfa was presented in the context of known information on alfalfa's: biology; breeding and genetics; out-crossing (gene flow) potential; geographical distribution, center of species origin and historical importance; agronomic cultural practice; commercial/industrial practice; end-product utilization, processing and distribution; and, economic and environmental valuation. Monsanto and FGI have provided USDA-APHIS-BRS and U.S. Environmental Protection Agency (EPA) with a detailed plan summary for trait stewardship post-commercialization. Stewardship plans for Roundup Ready alfalfa were built on Monsanto's in-depth experience with successful trait stewardship in other crops.

In 2002, the EPA conducted an initial assessment of the proposed use of glyphosate on Roundup Ready alfalfa as compared to the existing weed control strategies for alfalfa production. The EPA's analysis provided support for a reduction in the potential risks to human health and the environment with the use of glyphosate, in a Roundup agricultural herbicide, as compared to some currently-used herbicides. As a result of the assessment, EPA granted Monsanto's request for expedited review under EPA's Reduced Risk program.

Safety assessments are currently under review in the U.S., Canada and Mexico and submissions are planned to Japan and other key importing countries. In the U.S. and elsewhere the public is involved in the regulatory agency decision-making process. Most of the documents and data used to make the safety assessments will be made available to the public for comment by the regulatory agencies.

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