Safety Assessment Summary of Genuity Roundup Ready 2Yield MON 89788 Soybean

Executive Summary

Ongoing developments in biotechnology and molecular-assisted breeding have enabled Monsanto to develop a second-generation glyphosate-tolerant soybean product: Genuity™ Roundup Ready 2 Yield® or MON 89788 sovbean (OECD Unique ID: MON-89788-1). Similar to the first generation product Roundup Ready[®] soybean, MON 89788 soybean will continue to provide growers with flexibility, simplicity, and cost effective weed control options. However, MON 89788 soybean and varieties containing the trait have the added potential to enhance yield and thereby further benefit farmers and the soybean industry. In 1996, Roundup Ready soybean was the first soybean product containing a biotechnology trait to be commercialized in the U.S. Roundup Ready soybean was produced by incorporation of the *cp4 epsps* coding sequence derived from the common soil bacterium Agrobacterium sp. strain CP4. The cp4 epsps coding sequence directs the production of the 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) that is much less sensitive to glyphosate inhibition than endogenous plant EPSPS. The CP4 EPSPS renders Roundup Ready soybean tolerant to glyphosate, which is the active ingredient in Roundup agricultural herbicides. The utilization of Roundup agricultural herbicides plus Roundup Ready soybean, collectively referred to as the Roundup Ready Soybean System (RRSS), has provided significant convenience in weed control, encouraged the use of conservation-tillage, and provided substantial positive economic benefits to farmers.

MON 89788 soybean was developed by introduction of the cp4 epsps gene cassette containing a promoter that has been used in other crops such as Roundup Ready Flex cotton (Fincher et al., 2003). In addition, the transformation was based on a new technique of Agrobacterium-mediated gene delivery to soybean meristem, where cells were induced directly to form shoots and give rise to plants (Martinell et al., 2002). This new technique allowed direct transformation of the gene cassette into elite soybean germplasm such as the Asgrow soybean variety A3244 (Paschal, 1997), which is known for its superior agronomic characteristics and high yielding properties (Tylka and Marett, 1999). Using elite germplasm as the base genetics, the superior agronomic characteristic of the A3244 soybean can be introgressed to other soybean varieties through crosses with MON 89788 soybean containing the *cp4 epsps* cassette. In general, MON 89788 soybean has been found to have a 4 to 7% yield advantage compared to 40-3-2 soybeans, in the same genetic background, while maintaining the weed control and crop safety benefits of the Roundup Ready Soybean System. As a result, MON 89788 soybean will be an excellent agronomic base trait for future breeding improvements and multi-trait products.

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