

Safety Assessment of Roundup Ready® Canola Event GT73

Executive Summary

Using modern biotechnology, Monsanto Company has developed Roundup Ready® canola plants (*Brassica napus*) that are tolerant to glyphosate, the active ingredient in Roundup® agricultural herbicides. Glyphosate is an inhibitor of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), a well-known enzyme of the shikimate pathway for aromatic amino acid biosynthesis that is ubiquitous in plants, fungi, and bacteria. Plants, including weeds, exposed to glyphosate are unable to produce aromatic amino acids and hence die. 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. Two genes were introduced into the canola genome to produce this product: the *cp4 epsps* gene, derived from the common soil bacterium *Agrobacterium* strain CP4, which encodes for the production of the CP4 EPSPS enzyme, and the *gox* gene from *Ochrobactrum anthropi* strain LBAA, which encodes for the production of the enzyme glyphosate oxidase (GOX). Both gene products, the CP4 EPSPS and GOX proteins, are expressed constitutively in the plant, and together they are responsible for conferring tolerance to glyphosate. Because CP4 EPSPS has a naturally high tolerance to inhibition by glyphosate, Roundup Ready canola plants continue to produce aromatic amino acids even after treatment with glyphosate. In addition, the GOX protein catalyzes the breakdown of glyphosate into glyoxylic acid and aminomethylphosphonic acid (AMPA).

The glyphosate tolerance of Roundup Ready canola has been demonstrated in field tests starting in 1992 and in additional field tests conducted throughout growing regions in the United States, Canada, Europe and Australia. Roundup Ready canola was first planted commercially in 1996 on 50,000 acres in Canada. In the 2000 growing season, approximately 5.4 million acres (2.2 million hectares) of Roundup Ready canola were planted in Canada and the USA. Growers planting Roundup Ready canola have reduced the number and amount of herbicides used to control economically destructive weeds that grow in their fields, especially cruciferous weeds that are difficult to control with conventional weed control methods in canola, and have thereby realized a savings in weed control costs. This reduction in herbicide use has benefited the environment and also allows growers to implement integrated weed management practices that are generally not possible when pre-plant or pre-emergent herbicides are used.

The following summary provides information on the methods used to develop Roundup Ready canola, and an overview of the food, feed and environmental safety studies that have been conducted. These include molecular characterization of the DNA inserted into Roundup Ready canola, an assessment of the safety of the introduced proteins, compositional analyses of the food and feed components to establish substantial equivalence to conventional canola varieties, feeding studies in broiler, rat, fish and quail, and an assessment of the environmental safety of this product.

These studies establish the food, feed and environmental safety of Roundup Ready canola by demonstrating the safety of the CP4 EPSPS and GOX proteins to humans and animals, establishing equivalent nutritional composition and wholesomeness of Roundup Ready canola compared to conventional canola varieties, and confirming that the potential impact of Roundup Ready canola on the environment is no different than conventional canola varieties.

Monsanto Company is a member of Excellence Through Stewardship® (ETS). Monsanto products are commercialized in accordance with ETS Product Launch Stewardship Guidance, and in compliance with Monsanto's Policy for Commercialization of Biotechnology-Derived Plant Products in Commodity Crops. This product has been approved for import into key export markets with functioning regulatory systems. Any crop or material produced from this product can only be exported to, or used, processed or sold in countries where all necessary regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted. Growers should talk to their grain handler or product purchaser to confirm their buying position for this product. Excellence Through Stewardship® is a registered trademark of Excellence Through Stewardship.

ALWAYS READ AND FOLLOW PESTICIDE LABEL DIRECTIONS. Roundup Ready® Technology contains genes that confer tolerance to glyphosate. Glyphosate will kill crops that are not tolerant to glyphosate. Roundup Ready® and Roundup® are registered trademarks of Bayer Group.

© 2019 Bayer Group. All Rights Reserved. This document is protected under national and international copyright law and treaties. This document and any accompanying material are for use only by the regulatory authority to which it has been submitted by Monsanto Company and its affiliates, collectively "Bayer Group", and only in support of actions requested by Bayer Group. Any other use, copying, or transmission, including internet posting, of this document and the materials described in or accompanying this document, without prior consent of Monsanto Company, is strictly prohibited; except that Monsanto Company hereby grants such consent to the regulatory authority where required under applicable law or regulation. The intellectual property, information and materials described in or accompanying this document are owned by Bayer Group, which has filed for or been granted patents on those materials. By submitting this document and any accompanying materials, Monsanto Company and the Bayer Group do not grant any party or entity any right or license to the information, material or intellectual property described or contained in this submission.