

January 2020

## Safety Assessment of Glyphosate-Tolerant MON 88302 Canola

Monsanto Company has developed a second-generation glyphosate-tolerant canola product, MON 88302, designed to provide growers with improved weed control through greater flexibility for glyphosate herbicide applications. MON 88302 canola produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products, via the incorporation of a *cp4 epsps* coding sequence. The CP4 EPSPS protein confers tolerance to the herbicide glyphosate, the active ingredient in the family of Roundup® agricultural herbicides. MON 88302 canola utilizes an improved promoter sequence to enhance CP4 EPSPS expression in male reproductive tissues (i.e., pollen), compared to the promoter used to drive CP4 EPSPS production in the first-generation product, Roundup Ready canola product (RT73). Enhanced CP4 EPSPS expression in the male reproductive tissues of MON 88302 canola allows the greater flexibility of glyphosate herbicide applications because MON 88302 plants can be sprayed with higher recommended rates of glyphosate and at later stages of plant development.

MON 88302 canola was intensively tested in the laboratory and across multiple field sites in the USA and Canada. Data from those studies were used to conduct the product safety assessment and achieve government regulatory approvals. The product safety was based on the following:

- A detailed molecular characterization of the introduced DNA demonstrated a single, intact copy of the transgenic insert in a single locus within the MON 88302 canola genome.
- The CP4 EPSPS protein in MON 88302 is identical to the CP4 EPSPS protein produced in several other commercially available crops that have been reviewed by USDA (and other global regulatory authorities) and previously deregulated (e.g., Roundup Ready soybean, Roundup Ready 2 Yield soybean, Roundup Ready corn 2, Roundup Ready canola, Roundup Ready cotton and Roundup Ready Flex cotton). The safety of CP4 EPSPS proteins present in biotechnology-derived crops has been thoroughly assessed and is the subject of numerous publications. The mode of action of CP4 EPSPS protein and how it confers glyphosate tolerance has been extensively studied and is well documented in peer reviewed publications.
- A compositional assessment confirmed that MON 88302 seed is compositionally equivalent to seed of conventional canola.
- An extensive evaluation of MON 88302 phenotypic and agronomic characteristics and environmental interactions demonstrated MON 88302 has no increased plant pest potential compared to conventional canola.
- An assessment of potential impact to non-target organisms (NTOs) and endangered species indicated that, under normal agricultural conditions, MON 88302 is unlikely to have adverse effects on these organisms, similar to conventional canola.
- Evaluation of MON 88302 using intended and current cultivation and management practices for canola showed that commercial production of MON 88302 will not significantly impact canola agronomic practices or land use.

These studies establish the food, feed and environmental safety of MON 88302 canola by demonstrating the safety of the CP4 EPSPS protein to humans and animals, establishing equivalent nutritional composition and wholesomeness of MON 88302 canola compared to conventional canola varieties, and

confirming that the potential impact of MON 88302 canola on the environment is no different than conventional canola varieties.

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and copy rights of the owner and third parties. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction and/or publishing and any commercial exploitation and use of this document or its contents without the permission of the owner of this document may therefore be prohibited and violate the rights of its owner.

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.