

Decision Document DD2010-81 Determination of the Safety of Monsanto Canada Inc.'s Soybean (*Glycine max* (L.) Merr.) Event MON 87701

This Decision Document has been prepared to explain the regulatory decision reached under Directive 94-08 (Dir94-08), entitled "*Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*", its companion biology document BIO1996-10, "*The Biology of Glycine max* (L.) Merr. (*Soybean*)", and Chapter 2.6 of the Regulatory Guidance: Feed Registration Procedures and Labelling Standards, entitled "*Guidelines for the Assessment of Novel Feeds: Plant Sources*".

The Canadian Food Inspection Agency (CFIA) has evaluated information submitted by Monsanto Canada Inc. in regard to insect resistant soybean event MON 87701.

This plant with a novel trait (PNT) was assessed by the Plant and Biotechnology Risk Assessment Unit (PBRA) of the CFIA for its environmental risk, including human health, having regard to weediness potential, gene flow, plant pest potential, impact on non target organisms and impact on biodiversity. Taking into account the intended use of this product, which does not include cultivation in Canada, the risk from incidental release of event MON 87701 into the environment was determined to be minimal.

The Animal Feed Division of the CFIA has determined that insect resistant soybean event MON 87701 does not present livestock feed safety concerns when compared to currently commercialized soybean varieties.

Taking into account the conclusion of the risk assessment and recognizing that incidental release into the environment could occur when this PNT is used as intended, unconfined release into the environment of soybean event MON 87701 and of any lines derived from it is therefore authorized by the Plant Biosafety Office of the Plant Health and Biosecurity Directorate as of October 15, 2010 on a condition that no sale of seed takes place in Canada. This condition is being applied to ensure that the PNT is used as intended.

Taking into account livestock feed evaluation, use as livestock feed of soybean event MON 87701 and of any lines derived from it is authorized by the Animal Feed Division of the Animal Health Directorate.

Authorizations of the soybean lines derived from the event MON 87701 are conditional on the following: (i) no inter-specific crosses are performed, (ii) the intended use(s) are similar, (iii) it is known, following thorough characterization, that these plants do not display any additional novel traits and are substantially equivalent to MON 87701 in terms of their specific use and safety for the environment, including human health, as well as livestock safety and (iv) the novel gene is expressed at a level similar to that of the authorized line.

Soybean event MON 87701 is subject to the same phytosanitary import requirements as its unmodified counterparts.