

PART II

COMMON FORMAT FOR RISK ASSESSMENT

(In accordance with Annex III of the Cartagena Protocol on Biosafety)

Risk assessment details

1. Country Taking Decision:	South Africa
2. Title:	Application for General Release of Genetically Modified Organisms in South Africa – MON 87701 × MON 89788 soybean
3. Contact details:	Bayer (Pty) Ltd. Bayer Southern Africa – Crop Science 27 Wrench Road Isando Kempton Park South Africa

LMO information

4. Name and identity of the living modified organism:	Combined trait soybean product MON 87701 × MON 89788
5. Unique identification of the living modified organism:	MON 87701-2 × MON-89788-1
6. Transformation event:	MON 87701 × MON 89788
7. Introduced or Modified Traits:	Chemical tolerance - Herbicide tolerance Pest resistance - Insect resistance
8. Techniques used for modification:	MON 87701 × MON 89788 soybean was obtained by conventional breeding of 2 single soybean products: MON 87701 and MON 89788.
9. Description of gene modification:	Conventional breeding techniques were used to develop MON 87701 × MON 89788, a combined-trait soybean product that produces the Cry1Ac protein derived from <i>B. thuringiensis</i> that provides protection from feeding damage caused by targeted lepidopteran pests, and 5-enolpyruvylshikimate-3-phosphate synthase protein from <i>Agrobacterium</i> sp. strain CP4 (<i>CP4 EPSPS</i>) that confers tolerance to glyphosate herbicide.

Characteristics of modification

10. Vector characteristics (Annex III.9(c)):	Not applicable, MON 87701 × MON 89788 was obtained through conventional breeding methods.
11. Insert or inserts (Annex III.9(d)):	The results of molecular analyses demonstrate MON 87701 and MON 89788 inserts and flanking regions are present and intact in the combined trait soybean product MON 87701 × MON 89788.

Recipient organism or parental organisms (Annex III.9(a)):

12. Taxonomic name/status of recipient organism or parental organisms:	Common name: Soybean (Soy) Family name: Fabaceae Genus: <i>Glycine</i> Willd. Species: <i>Glycine max</i> (L.) Merr
13. Common name of recipient organism or parental organisms:	Soybean
14. Point of collection or acquisition of recipient or parental organisms:	MON 87701 × MON 89788 was produced using elite parent lines into which the MON 87701 and MON 89788 events have been introgressed independently, using conventional breeding techniques. The original transformations that produced the individual events used privately owned germplasm acquired for this purpose.
15. Characteristics of recipient organism or parental organisms related to biosafety:	<p>Soybean is grown as a commercial crop in over 35 countries and is grown primarily for the production of seed, has a multitude of uses in the food and industrial sectors, and represents one of the major sources of edible vegetable oil and of proteins for livestock feed use.</p> <p>Soybean is considered a self-pollinated species, propagated commercially by seed. Neither the seedpod, nor the seed, has morphological characteristic that would encourage animal transportation.</p> <p>Cultivated soybean seed rarely displays any dormancy characteristics and only under certain environmental conditions grows as a volunteer in the year following cultivation. If this should occur, volunteers do not compete well with the succeeding crop, and can easily be controlled mechanically or chemically. The soybean plant is not weedy in character.</p>
16. Centre(s) of origin of recipient organism or parental organisms:	Soybean is commonly considered one of the oldest cultivated crops, native to North and Central China.
17. Centre(s) of genetic diversity, if known, of recipient organism or parental organisms:	Refer to point 16 above

26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<p>MON 87701 × MON 89788 is considered as safe as conventional soybean, based on the following –</p> <ul style="list-style-type: none"> • The inserted genes in MON 87701 × MON 89788 are stably integrated. • The safety assessment of the proteins produced in MON 87701 × MON 89788 includes protein characterization, functional and structural comparisons of the proteins to ubiquitous plant and microbial proteins with a history of safe consumption, <i>in vitro</i> digestibility in simulated gastric and intestinal fluids, acute oral toxicity in mice, and amino acid comparison to known toxins and allergens. • Compositional analysis demonstrated that food and feed components from MON 87701 × MON 89788 are substantially equivalent to that of the conventional soybean, except for the intentionally introduced traits. • The plant phenotypic characteristics and environmental interactions evaluation demonstrated that MON 87701 × MON 89788 is not meaningfully different from conventional soybean and is not expected to pose a plant pest risk compared to conventional soybean. • Studies demonstrate that the proteins are safe to non-target organisms, including humans, animals, and beneficial insects.
27. Evaluation of the consequences (Annex III.8(c)):	Considering the safety assessment conducted for MON 87701 × MON 89788, the potential risk of adverse consequences is considered to be negligible.
28. Overall risk (Annex III.8(d)):	Considering the potential risks and the consequences should the potential risks materialize the overall risk of importing, cultivating or field testing MON 87701 × MON 89788 is extremely low.
29. Recommendation (Annex III.8(e)):	No risks have been identified and therefore other than the containment parameters that might apply through the permit conditions, no additional actions need to be taken.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	The potential risks for the specific product is negligible; hence no additional actions are required except compliance with the conditions contained in the permit.
Additional information	
31. Availability of detailed risk assessment information:	More information regarding the safety of MON 87701 × MON 89788 is contained in the application preceding this section.
32. Any other relevant information:	None
33. Attach document:	Not applicable to applicant
34. Notes:	None