

**PART II**

**COMMON FORMAT FOR RISK ASSESSMENT**  
(In accordance with Annex III of the Cartagena Protocol on Biosafety)

<b>Risk assessment details</b>	
1. Country Taking Decision:	South Africa
2. Title:	Application for Commodity Clearance of Genetically Modified Organisms (GMO) – MON 87751 × MON 87701 × MON 87708 × MON 89788
3. Contact details:	Monsanto Company, represented by Monsanto S.A.(Pty) Ltd  Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 USA  Monsanto House, Building No. 4 Fourways Office Park Corner Fourways Boulevard and Roos Streets Fourways South Africa
<b>LMO information</b>	
4. Name and identity of the living modified organism:	Combined trait product MON 87751 × MON 87701 × MON 87708 × MON 89788
5. Unique identification of the living modified organism:	MON 87751-7 × MON 87701-2 × MON-87708-9 × MON-89788-1
6. Transformation event:	MON 87751 × MON 87701 × MON 87708 × MON 89788
7. Introduced or Modified Traits:	<b>Chemical tolerance</b> - Herbicide tolerance  <b>Pest resistance</b> - Insect resistance
8. Techniques used for modification:	MON 87751 × MON 87701 × MON 87708 × MON 89788 soybean was obtained by conventional breeding of 4 single soybean products: MON 87751, MON 87701, MON 87708 and MON 89788.
9. Description of gene modification:	Monsanto Company has developed the combined trait soybean product MON 87751 × MON 87701 × MON 87708 × MON 89788, through conventional breeding of MON 87751, MON 87701, MON 87708, and MON 89788. MON 87751 produces the Cry1A.105 and Cry2Ab2 insecticidal crystal (Cry) proteins (δ-endotoxin) derived from <i>Bacillus thuringiensis</i> . MON 87701 produces the Cry1Ac protein also derived from <i>B. thuringiensis</i> . The Cry1A.105, Cry2Ab2 and Cry1Ac proteins provide protection from feeding damage caused by targeted lepidopteran pests. MON 87708 is a dicamba-tolerant soybean that produces a dicamba mono-oxygenase (DMO) protein from <i>Stenotrophomonas maltophilia</i> to confer tolerance to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide. MON 89788 is a glyphosate-tolerant soybean that produces 5-enolpyruvylshikimate-3-phosphate synthase protein from <i>Agrobacterium</i> sp. strain CP4 (CP4 EPSPS) to confer tolerance to glyphosate herbicide.
<b>Characteristics of modification</b>	

10. Vector characteristics (Annex III.9(c)):	Not applicable, MON 87751 × MON 87701 × MON 87708 × MON 89788 was obtained through conventional breeding methods.
11. Insert or inserts (Annex III.9(d)):	The DNA sequence of the MON 87751, MON 87701, MON 87708 and MON 89788 inserts in MON 87751 × MON 87701 × × MON 87708 MON 89788 are identical to the DNA sequences determined for the single events MON 87751, MON 87701, MON 87708, and MON 89788. The results of molecular analyses demonstrate MON 87751, MON 87701, MON 87708 and MON 89788 inserts and flanking regions are present and intact in the combined trait soybean product MON 87751 × MON 87701 × MON 87708 × MON 89788.
<b>Recipient organism or parental organisms (Annex III.9(a)):</b>	
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 87751 × MON 87701 × MON 87708 × MON 89788 was produced using elite parent lines into which the MON 87751, MON 87701, MON 87708 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:	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.  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.  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.
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

18. Habitats where the recipient organism or parental organisms may persist or proliferate:	<p>Soybean is an annual crop that is planted in late spring from April to May in the northern hemisphere, and from November to February in the southern hemisphere. Soybean seed germinates when the soil temperature reaches 10°C and emerges in a 5-7 day period under favourable conditions (OECD, 2000). Soybean grows most rapidly when air temperatures are between 25°C and 35°C (Beverdors, 1993). During the reproductive stages of development, soybean plants are particularly sensitive to hydric and thermal (low temperature) stress which can cause significant flower abortion and yield loss (CETIOM, 1987). Soybean does not yield well on acid soils and the addition of limestone may be required (OECD, 2000).</p> <p>The life cycle of soybean is approximately 100 to 160 days, depending on the variety and the region in which it is cultivated (CETIOM, 1987).</p> <p>Soybean cultivars are identified based on bands of adaptation that run east-west, determined by latitude and day length (OECD, 2000). They are classified into one of 13 maturity groups (000, 00, 0, I to X), which determines the area where it will be most productive (Palmer and Kilen, 1987). As soybean is a short day plant, time to maturity is strongly influenced by photoperiod.</p>
<b>Donor organism or organisms (Annex III.9(b)):</b>	
19. Taxonomic name/status of donor organism(s)	<p><i>Bacillus thuringiensis</i>  <i>Agrobacterium tumefaciens</i> strain CP4  <i>Stenotrophomonas maltophilia</i></p>
20. Common name of donor organism(s):	Bacteria
21. Point of collection or acquisition of donor organism(s):	The organisms are ubiquitous in nature
22. Characteristics of donor organism(s) related to biosafety:	Not applicable, since the donor organisms are ubiquitous in nature and therefore do not pose a threat to biodiversity.
<b>Intended use and receiving environment</b>	
23. Intended use of the LMO (Annex III 9(g)):	This is an application for Commodity Clearance of MON 87751 × MON 87701 × MON 87708 × MON 89788
24. Receiving environment (Annex III.9(h)):	This is an application for Commodity Clearance therefore the product will not be cultivated in South Africa.
<b>Risk assessment summary</b>	
25. Detection/Identification method of the LMO (Annex III.9(f)):	<p>Methods for detection of MON 87751, MON 87701, MON 87708 and MON 89788 DNA have been provided to the Registrar. This information is regarded to be business confidential and Monsanto has intellectual property rights that govern the use of each event specific detection method in the Republic of South Africa. DAFF shall use the information solely for the purpose of facilitating or permitting regulatory approval under the Genetically Modified Organism Act, Act 15 of 1997 and to carry out or enforce the requirements of those other laws of the Republic of South Africa which regulate MON 87751 × MON 87701 × MON 87708 × MON 89788 and its use, and for no other purpose.</p>

26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<p>MON 87751 × MON 87701 × MON 87708 × MON 89788 is considered as safe as conventional soybean, based on the following –</p> <ul style="list-style-type: none"> <li>• The inserted genes in MON 87751 × MON 87701 × MON 87708 × MON 89788 are stably integrated.</li> <li>• The safety assessment of the proteins produced in MON 87751 × MON 87701 × MON 87708 × 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.</li> <li>• Compositional analysis demonstrated that food and feed components from MON 87751 × MON 87701 × MON 87708 × MON 89788 are substantially equivalent to that of the conventional soybean, except for the intentionally introduced traits.</li> <li>• The plant phenotypic characteristics and environmental interactions evaluation demonstrated that MON 87751 × MON 87701 × MON 87708 × MON 89788 is not meaningfully different from conventional soybean and is not expected to pose a plant pest risk compared to conventional soybean.</li> <li>• Studies demonstrate that the proteins are safe to non-target organisms, including humans, animals, and beneficial insects.</li> </ul>
27. Evaluation of the consequences (Annex III.8(c)):	Considering the safety assessment conducted for MON 87751 × MON 87701 × MON 87708 × 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 87751 × MON 87701 × MON 87708 × 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.
<b>Additional information</b>	
31. Availability of detailed risk assessment information:	More information regarding the safety of MON 87751 × MON 87701 × MON 87708 × 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