12. Risk Assessment (Annex III of the Cartegena Protocol on Biosafety)

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 Commodity Clearance of Genetically Modified Organisms (GMO) - MON 87705 × 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
	LMO information	
4.	Name and identity of the living modified organism:	Multi-event stack MON 87705 × MON 87708 × MON 89788
5.	Unique identification of the living modified organism:	MON-877Ø5-6 × MON-877Ø8-9 × MON-89788-1
6.	Transformation event:	MON 87705 × MON 87708 × MON 89788
7.	Introduced or Modified Traits:	B. Altered growth, development and product quality **Nutritional composition** **Chemical tolerance** - Herbicide tolerance
8.	Techniques used for modification:	MON 87705 × MON 87708 × MON 89788 soybean was obtained by conventional breeding of three single soybean products, MON 87705, MON 87708 and MON 89788, Genetic modification was used in the development of the parental soybean lines.

9. Description of gene modification:	Conventional breeding techniques were used to develop MON 87705 × MON 87708 × MON 89788, a combined-trait soybean product. Each biotechnology-derived trait contributes specific benefits to the final combined product as follows: MON 87705 is a nutritionally enhanced soybean product with decreased levels of saturated fats (16:0 palmitic acid and 18:0 stearic acid) and increased levels of 18:1 oleic acid with an associated decrease in 18:2 linoleic acid. This improved oil is produced in the soybean through biotechnology-mediated gene suppression of FATB and FAD2, two key enzymes in the fatty acid biosynthetic pathway. Suppression of the FATB enzyme results in a decrease in the levels of saturated fats (16:0 palmitic acid and 18:0 stearic acid), while suppression of the FAD2 enzyme results in an increase of oleic acid (18:1) and associated decrease in linoleic acid (18:2). Oil from MON 87705 has enhanced storage and processing stability, an improved nutritional profile, and better food functionality. MON 87705 also contains the *5-enolpyruvylshikimate-3-phosphate synthase* gene derived from *Agrobacterium sp.* strain CP4 (*cp4 epsps*). Expression of the gene product (CP4 EPSPS) confers tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides. The *cp4 epsps* gene was used as a selectable marker during plant transformation. MON 87708 is a dicamba-tolerant soybean that produces a dicamba mono-oxygenase (DMO) protein from *Stenotrophomonas maltophilia* 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 *Agrobacterium sp.* strain CP4 (CP4 EPSPS) to confer tolerance to glyphosate herbicide.
Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	Not applicable, MON 87705 × MON 87708 × MON 89788 was obtained through conventional breeding methods.

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11. Insert or inserts (Annex III.9(d)):	Like MON 87705, MON 87705 × MON 87708 × MON 89788 produces soybean seeds with decreased levels of saturated fatty acids (16:0 palmitic acid and 18:0 stearic acid) and increased level of monounsaturated fatty acid (18:1 oleic acid) with an associated decrease in the level of the polyunsaturated 18:2 linoleic acid, as well as the CP4 EPSPS protein conferring tolerance to glyphosate-containing herbicides. Like MON 87708, MON 87705 × MON 87708 × MON 89788 expresses dicamba mono-oxygenase (DMO) protein from *Stenotrophomonas maltophilia* to confer tolerance to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide. Like MON 89788, MON 87705 × MON 87708 × MON 89788 expresses the CP4 EPSPS protein isolated from *Agrobacterium sp.* strain CP4, which confers tolerance to glyphosate, the active ingredient in the Roundup®Error! Bookmark not defined. family of agricultural herbicides.
Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	Common name: Soybean Family name: Leguminosae Genus: *Glycine* Willd Species: *Glycine max* L.
13. Common name of recipient organism or parental organisms:	Soybean
14. Point of collection or acquisition of recipient or parental organisms:	MON 87705 × MON 87708 × MON 89788 was produced using elite parent lines into which the MON 87705, 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:	Wild soybean species are endemic in China, Korea, Japan and Taiwan.

17. Centres 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:	Soybean is a quantitative short day plant and hence flowers more quickly under short days (Garner and Allard 1920). As a result, photoperiodism and temperature response is important in determining areas of cultivar adaptation. Soybean cultivars are identified based on bands of adaptation that run east-west, determined by latitude and day length. Soybean seed will germinate when the soil temperature reaches 10°C and will emerge in a 5-7 day period under favourable conditions.
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	MON 87705 × MON 87708 × MON 89788 was obtained from conventional breeding of the single events MON 87705, MON 87708 and MON 89788. The donor organisms used in development of the single events were *Stenotrophomonas maltophilia* (MON 87708) and *Agrobacterium tumefaciens* strain CP4 (MON 87705 and MON 89788).
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.
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	The intent of this application is for the commodity import of soybean containing MON 87705 × 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.
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	MON 87705 × MON 87708 × MON 89788 was produced by crossing plants containing MON 87705, MON 87708 and MON 89788, using conventional breeding methods. Therefore, MON 87705 × MON 87708 × MON 89788 is detectable using the combination of the single event-specific PCR method for detecting the introduced DNA present in the single events MON 87705 × MON 87708 × MON 89788. Event specific detection methods for detection of MON 87705, MON 87708 and MON 89788 DNA accompany this application. The detection methods are considered trade secret and Monsanto has intellectual property rights that govern the use of each event specific detection method in the Republic of South Africa.

26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	Based on the nature of the recipient species (unable to proliferate) and the lack of related and wild species with which MON 87705 × MON 87708 × MON 89788 can outcross, the likelihood of adverse effects from out-crossing to other related species is negligible. Transgenic soybean varieties with similar genes have been grown around the world and in South Africa for several years without any recorded impact on the environment other than those created by conventional soybean production. Any volunteers could, like conventional soybean, be removed by current agricultural practices such as ploughing and the use of herbicides.
27. Evaluation of the consequences (Annex III.8(c)):	Studies conducted with MON 87705 × MON 87708 × MON 89788 confirmed that this mutli-event stack is agronomically and compositionally equivalent to conventional soybean and has no increased tendency towards weediness or an increased susceptibility of tolerance to insects normally associated with soybean. Thus, should any of the potential risks materialize, the consequences would be negligible. No potentially adverse effects were detected based on extensive characterization of MON 87705 × MON 87708 × MON 89788, which included molecular analysis, expression analysis, compositional analyses and phenotypic evaluation. Testing of MON 87705 × MON 87708 × MON 89788 demonstrated no changes in its ability to persist in the environment without human intervention or to become invasive compared to conventional soybean. As such, the potential consequences to biodiversity resulting from MON 87705 × MON 87708 × MON 89788 for commercial use, including food, feed or processing, are the same as with conventional soybean. Any volunteer seed germinating in subsequent growing seasons would be detected in the fields that were planted and destroyed using chemical or mechanical means.
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 87705 × 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.
Additional information	
31. Availability of detailed risk assessment information:	More information regarding the safety of MON 87705 × 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