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PART II: Risk Assessment

	Risk assessment details	
1.	**Country Taking Decision:**	South Africa
2.	**Title:**	Application for Commodity Clearance of MON 87708 X MON 89788 in South Africa
3.	**Contact details:**	Monsanto South Africa (Pty) Ltd P.O. Box 69933, Bryanston 2010
	LMO information	
4.	**Name and identity of the living modified organism:**	Soybean event MON 87708 X MON 89788
5.	**Unique identification of the living modified organism:**	MON-877Ø8-9 x MON-89788-1
6.	**Transformation event:**	MON 87708 X MON 89788
7.	**Introduced or Modified Traits:**	Dicamba & Glyphosate Herbicide Tolerance
8.	**Techniques used for modification:**	MON 87708 × MON 89788 is produced by crossing soybean plants containing MON 87708 and MON 89788, using traditional breeding methods. F_1 seed thereby inherits the dicamba and glyphosate-tolerance traits from MON 87708 and MON 89788, respectively. While MON 87708 × MON 89788 results from traditional breeding, genetic modification was used in the development of the parental lines MON 87708 and MON 89788. Both parental lines were developed through *Agrobacterium*-mediated transformation of soybean tissues. MON 87708 produces DMO proteins which impart tolerance to dicamba. MON 89788 contains a fully functional intact gene encoding the CP4 EPSPS protein, which confers tolerance to glyphosate.

9. Description of gene modification:	Like MON 87708, MON 87708 × MON 89788 produces the MON 87708 DMO proteins which impart tolerance to dicamba. Like MON 89788, MON 87708 × MON 89788 expresses the CP4 EPSPS protein which imparts tolerance to glyphosate.
Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	MON 87708 was developed through *Agrobacterium tumefaciens*-mediated transformation of conventional soybean A3525 meristem tissue with the 2T-DNA plasmid vector PV-GMHT4355. *Agrobacterium*-mediated transformation is a well-documented process for the transfer and integration of exogenous DNA into a plant's nuclear genome (Bevan, 1984). PV-GMHT4355 is approximately 11.4 kb and contains two separate transfer DNAs (T-DNA), each delineated by Left and Right Border sequences to facilitate transformation. The first T-DNA, designated as T-DNA I, contains the *dmo* coding sequence under regulation of the peanut chlorotic streak virus (*PC1SV*) promoter and the pea *E9* 3′ non-translated region. The second T-DNA, designated as T-DNA II, contains the *cp4 epsps* coding sequence under the regulation of the figwort mosaic virus (*FMV*) promoter and the pea *E9* 3′ non-translated region. During transformation, both T-DNAs were inserted into the soybean genome, where T-DNA II, containing the *cp4 epsps* expression cassette, functioned as a marker gene for the selection of transformed plantlets. Subsequently, conventional self-pollination breeding methods and segregation, along with a combination of analytical techniques, were used to isolate those plants that contain the *dmo* expression cassette (T-DNA I) and did not contain the *cp4 epsps* expression cassette (T-DNA II), resulting in the production of marker-free, dicamba-tolerant soybean MON 87708. Molecular characterization of MON 87708 by Southern blot analyses demonstrated that MON 87708 contains a single copy of the *dmo* expression cassette (T-DNA I) integrated at a single locus of the soybean genome in MON 87708. There were no additional genetic elements, including T-DNA II and backbone sequences, from the transformation vector PV-GMHT4355, linked or unlinked to the intact DNA insert, in MON 87708. **MON 89788** MON 89788 was developed through *Agrobacterium*-mediated transformation of soybean meristem tissue using the double-border, binary vector PV-GMGOX20. This vector is approximately 9.7 kb. The T-DNA is delineated by the right and left border regions and is approximately 4.3 kb. It hosts the *cp4 epsps* expression cassette and is intended for incorporation into the soybean genome. The

	DNA backbone region outside the T-DNA is approximately 5.4 kb and is not meant to be transferred into the soybean genome. Molecular analysis of MON 89788 supported the following conclusions: • The DNA is inserted into the soybean genome at a single locus. • The insert contains one intact copy of the *cp4 epsps* expression cassette. • No additional elements from the transformation vector PV-GMGOX20, linked or unlinked to the T-DNA, were detected. • No element of the PV-GMGOX20 backbone sequence was detected. • PCR and DNA sequence analyses confirmed the organization and intactness of the elements within the MON 89788 insert. • The generational stability analysis demonstrated that the expected Southern blot fingerprint of MON 89788 has been maintained across multiple generations. • Heritability and stability of the glyphosate-tolerance phenotype were as expected across multiple generations, which corroborates the molecular insert stability analysis and establishes the genetic behaviour of the MON 89788 insert at a single chromosomal locus. **MON 87701 x MON 89788** The genome of MON 87708 × MON 89788 contains two different inserts, one derived from MON 87708 and one derived from MON 89788. There is low likelihood of molecular interactions between the inserts from MON 87708 and MON 89788 and, therefore, low likelihood of any changes in the molecular characteristics of the inherited inserts in MON 87708 × MON 89788 (*e.g.* insert number, copy number, absence of backbone DNA and integrity of the individual inserts)
11. Insert or inserts (Annex III.9(d)):	The single DNA insert from the genome of MON 87708, contains a single copy of the *dmo* expression cassette (T-DNA I) integrated at a single locus of the soybean genome in MON 87708. There were no additional genetic elements, including T-DNA II and backbone sequences, from the transformation vector PV-GMHT4355, linked or unlinked to the intact DNA insert, in MON 87708. The single DNA insert from the genome of MON 89788, containing the *cp4 epsps* cassette consisting of: the FMV/Tsf1 chimeric promoter (1.04 kb), the *Tsf1* leader (0.05 kb) and intron (0.62 kb), the *CTP2* targeting sequence (0.23kb), the *cp4 epsps* coding sequence (1.37 kb), the *E9* transcript termination sequence (0.64 kb).

Recipient organism or parental organisms (Annex III.9(a)):		
12. Taxonomic name/status of recipient organism or parental organisms:	Common name: Family name: Genus: Species:	Soybean Leguminosae Glycine Willd *Glycine max* L.
13. Common name of recipient organism or parental organisms:	Soybean	
14. Point of collection or acquisition of recipient or parental organisms:	The original transformations that produced MON 87708 X MON 89788 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:	Please refer to the response in section 16.	

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)	*Agrobacterium tumefaciens strain CP4* *Stenotrophomonas maltophilia*
20. Common name of donor organism(s):	*Agrobacterium tumefaciens* are common soil bacteria that may cause crown gall disease in certain plants. *S. maltophilia* is ubiquitous in the environment and is found associated with the rhizosphere of plants
21. Point of collection or acquisition of donor organism(s):	Organisms are ubiquitous in nature.
22. Characteristics of donor organism(s) related to biosafety:	The donor organisms are ubiquitous in nature.
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	This is an application for commodity clearance approval of MON 87708 X MON 89788.
24. Receiving environment (Annex III.9(h)):	Except for the specifically introduced herbicide tolerant traits, MON 87708 X MON 89788 is equivalent to conventional soybean. With this application, MON 87708 X MON 89788 is destined for use as food, feed and in processing. No environmental release is proposed. In the unlikely event that some soybean should end up in the environment, no differences in ecological impact are anticipated.
	Risk assessment summary
25. Detection/Identification method of the LMO (Annex III.9(f)):	An event specific detection method for detection of MON 89788 & MON 87708 DNA has been validated by the European Commission Joint Research Centre (EU JRC), and is available on the EU JRC website at: http://gmo-crl.jrc.ec.europa.eu/summaries
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	MON 87708 X MON 89788 is considered as safe as conventional soybean, based on the following – • The inserted genes in MON 87708 X MON 89788 are stably integrated.

	• The safety assessment of the proteins produced in MON 87708 X MON 89788 includes protein characterization, functional and structural comparisons of the proteins to ubiquitous plant and microbial proteins with a history of safe consumption, *in vitro* 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 seed and food components from MON 87708 X MON 89788 are substantially equivalent to soybean seed and food components from conventional soybean varieties. • 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 87708 X MON 89788, the potential risk of adverse consequences is considered to be negligible.
28. Overall risk (Annex III.8(d)):	The overall risk of using MON 87708 X MON 89788 as food, feed or in processing is considered to be the same as the risk of using conventional soybean as food, feed or in processing.
29. Recommendation (Annex III.8(e)):	No risk management measures are required, except for the measures that will be applicable to imported soybean consignments.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	There is no uncertainty regarding the risk profile.
Additional information	
31. Availability of detailed risk assessment information:	Information pertaining to the detailed risk assessment is contained in the application (Part I).
32. Any other relevant information:	None.
33. Attach document:	*Not applicable to applicant*
34. Notes:	See references below.

References:

Garner, W. W. and H. A. Allard 1920 Effect of the relative length of day and night and other factors of the environment on growth and reproduction of plants. *J. Agric. Res.* 18: 553-606.

Bevan M, 1984. Binary *Agrobacterium* vectors for plant transformation. Nucleic Acids Res., 12, 8711-8721.