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**PART II: Risk Assessment**

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<b>Risk assessment details</b>	
<b>1. Country Taking Decision:</b>	South Africa
<b>2. Title:</b>	Commodity Clearance of MON 89788
<b>3. Contact details:</b>	Monsanto South Africa (Pty) Ltd P.O. Box 69933, Bryanston 2010
<b>LMO information</b>	
<b>4. Name and identity of the living modified organism:</b>	Soybean event MON 89788
<b>5. Unique identification of the living modified organism:</b>	MON-89788-1
<b>6. Transformation event:</b>	MON 89788
<b>7. Introduced or Modified Traits:</b>	Herbicide tolerance
<b>8. Techniques used for modification:</b>	MON 89788 was developed through <i>Agrobacterium</i> -mediated transformation of soybean meristem tissue using the double-border, binary vector PV-GMGOX20. PV-GMGOX20 includes a region of DNA named transfer DNA (T-DNA), which hosts the <i>cp4 epsps</i> expression cassette and is intended for incorporation into the soybean genome.
<b>9. Description of gene modification:</b>	MON 89788 was developed through <i>Agrobacterium</i> -mediated transformation of soybean meristem tissue and contains a fully functional intact gene encoding the CP4 EPSPS protein, which confers tolerance to glyphosate.
<b>Characteristics of modification</b>	
<b>10. Vector characteristics (Annex III.9(c)):</b>	The PV-GMGOX20 vector was used for the transformation of soybean meristem to produce MON 89788. 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 <i>cp4 epsps</i> expression cassette and is intended

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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.

The *cp4 epsps* expression cassette comprised between the right and left borders of the T-DNA consists of *FMV/Tsf1*, a chimeric promoter containing enhancer sequences to regulate constitutive expression (Axelos *et al.*, 1989; Richins *et al.*, 1987); the *Tsf1* leader and intron sequence to enhance the expression of the *CTP2/cp4 epsps* coding sequence; the *CTP2* transit peptide to direct the transport of the CP4 EPSPS protein to the chloroplast (Axelos *et al.*, 1989); the *cp4 epsps* coding sequence encoding the CP4 EPSPS protein that confers tolerance to glyphosate (Barry *et al.*, 1997; Padgett *et al.*, 1996) and the *E9* 3' nontranslated sequence that directs transcriptional termination and polyadenylation of the *CTP2/cp4 epsps* mRNA (Coruzzi *et al.*, 1984).

Four genetic elements exist outside of the T-DNA borders that are essential for the maintenance and selection of plasmid vector PV-GMGOX20 in bacteria. They include: *ori V*, the origin of replication for maintenance of the plasmid in *Agrobacterium* (Stalker *et al.*, 1981); *rop*, the coding sequence for the repressor of primer (ROP) protein to maintain the plasmid copy number in *E. coli* (Giza and Huang, 1989); *ori-PBR322*, the origin of replication from pBR322 for maintenance of the plasmid in *E. coli* (Sutcliffe, 1978) and *aadA*, a bacterial gene from transposon Tn7 that confers spectinomycin and streptomycin resistance for molecular cloning and selection purposes prior to plant transformation (Fling *et al.*, 1985). As these elements are outside of the border regions, they are not expected to be transferred into the soybean genome.

**11. Insert or inserts  
(Annex III.9(d)):**

The PV-GMGOX20 vector was used for the transformation of soybean meristem to produce MON 89788. The T-DNA hosts the *cp4 epsps* expression cassette and is intended for incorporation into the soybean genome.

**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:	<i>Glycine max</i> L.

**13. Common name of recipient organism or parental organisms:**

Soybean

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<b>14. Point of collection or acquisition of recipient or parental organisms:</b>	The original transformations that produced MON 89788 used privately owned germplasm acquired for this purpose.
<b>15. Characteristics of recipient organism or parental organisms related to Biosafety:</b>	<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>
<b>16. Centre(s) of origin of recipient organism or parental organisms:</b>	Wild soybean species are endemic in China, Korea, Japan and Taiwan.
<b>17. Centres of genetic diversity, if known, of recipient organism or parental organisms:</b>	Please refer to the response in section 16.
<b>18. Habitats where the recipient organism or parental organisms may persist or proliferate:</b>	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.
<b>Donor organism or organisms (Annex III.9(b)):</b>	
<b>19. Taxonomic name/status of donor organism(s)</b>	<i>Agrobacterium tumefaciens strain CP4</i>

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<b>20. Common name of donor organism(s):</b>	<i>Agrobacterium tumefaciens</i> are common soil bacteria that may cause crown gall disease in certain plants.
<b>21. Point of collection or acquisition of donor organism(s):</b>	Organisms are ubiquitous in nature.
<b>22. Characteristics of donor organism(s) related to biosafety:</b>	The donor organism is ubiquitous in nature.
<b>Intended use and receiving environment</b>	
<b>23. Intended use of the LMO (Annex III 9(g)):</b>	This is an application for commodity clearance approval of MON 89788.
<b>24. Receiving environment (Annex III.9(h)):</b>	Except for the specifically introduced herbicide tolerant trait, MON 89788 is equivalent to conventional soybean. With this application, 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.
<b>Risk assessment summary</b>	
<b>25. Detection/Identification method of the LMO (Annex III.9(f)):</b>	An event specific detection method for detection of MON 89788 DNA has been validated by the European Commission Joint Research Centre (EU JRC), and is available on the EU JRC website at: <a href="http://gmo-crl.jrc.ec.europa.eu/summaries/MON89788_validated_Method.pdf">http://gmo-crl.jrc.ec.europa.eu/summaries/MON89788_validated Method.pdf</a>
<b>26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):</b>	MON 89788 is considered as safe as conventional soybean, based on the following – <ul style="list-style-type: none"><li>• The inserted <i>cp4 epsps</i> gene in MON 89788 is stably integrated.</li><li>• The safety assessment of the CP4 EPSPS protein produced in MON 89788 includes protein characterization, functional and structural comparisons of the CP4 EPSPS protein to ubiquitous plant and microbial EPSPS 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 seed and food components from MON 89788 are substantially equivalent to soybean seed and food components from conventional soybean varieties.</li><li>• Studies demonstrate that the CP4 EPSPS protein</li></ul>

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	is safe to non-target organisms, including humans, animals, and beneficial insects.
<b>27. Evaluation of the consequences (Annex III.8(c)):</b>	Considering the safety assessment conducted for MON 89788, the potential risk of adverse consequences is considered to be negligible.
<b>28. Overall risk (Annex III.8(d)):</b>	The overall risk of using 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.
<b>29. Recommendation (Annex III.8(e)):</b>	No risk management measures are required, except for the measures that will be applicable to imported soybean consignments.
<b>30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):</b>	There is no uncertainty regarding the risk profile.
<b>Additional information</b>	
<b>31. Availability of detailed risk assessment information:</b>	Information pertaining to the detailed risk assessment is contained in the application (Part I).
<b>32. Any other relevant information:</b>	None.
<b>33. Attach document:</b>	<i>Not applicable to applicant</i>
<b>34. Notes:</b>	See references below.

**References:**

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