agriculture,
forestry & fisheries
Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

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APPLICATION FOR INTENTIONAL INTRODUCTION (CONDUCT A TRIAL RELEASE) OF GENETICALLY MODIFIED ORGANISMS (GMOs) INTO THE ENVIRONMENT OF SOUTH AFRICA

PART I (to be completed for all GMOs)

1. APPLICANT

1.1 Name of applicant
1.2 Address of applicant

2. BRIEF DESCRIPTION OF THE GMO

Provide a brief description of the GMO, the intended function(s) of the genetic modification(s), and the GM trait(s) of the GMO.

3. BRIEF DESCRIPTION OF THE PROPOSED TRIAL RELEASE

3.1 Provide a brief description of the proposed trial release.

3.2 What is the aim of the proposed trial release of the GMO?

4. CHARACTERISTICS OF THE HOST OR UNMODIFIED RECIPIENT ORGANISM

4.1 Specific and common names of the unmodified recipient or host organism.

4.2 Natural habitat, geographic distribution, geographic origin, and centres for diversity.

4.3 Does the unmodified recipient organism or host have any adverse effect on:

4.3.1 Humans
4.3.2 Animals
4.3.3 Plants
4.3.4 Agricultural production
4.3.5 Any other aspect of the environment.

4.4 Reproduction:

4.4.1 Provide detailed information on the mode(s) of reproduction.
4.4.2 Provide detailed information on specific factors affecting reproduction.
4.4.3 Provide detailed information on the generation time.

4.5 Survivability in the environment:

4.5.1 Provide details on structures produced by the host or unmodified recipient for survival or dormancy.
4.5.2 Provide information on specific factors affecting survivability.

4.6 Dissemination in the environment:

4.6.1 Provide details on how the the host or unmodified recipient may disseminate in the environment.
4.6.2 Provide information on specific factors affecting dissemination.

4.7 Provide information on how the the host or unmodified recipient is usually utilised in agriculture, forestry, medicine, etc.

5. INSERTED OR DELETED NUCLEIC ACID SEQUENCES AND THE GMO

5.1 Scientific and common names of the donor organism(s).

5.2 Natural habitat, geographic distribution, geographic origin, and centres for diversity of the donor organism(s).

5.3 Provide information on the nucleic acid sequence(s) inserted or deleted in the GMO:

5.3.1 In the case of insertion(s), a description of the inserted nucleic acid sequence(s), size and function.
5.3.2 Describe the gene product(s) that are derived from the inserted gene(s).
5.3.3 Describe the biological activity associated with the inserted sequences or their encoded products.
5.3.4 In the case of insertion(s), the copy number of all detectable inserts, both complete and partial.
5.3.5 In the case of deletion(s), a description of the deleted region(s), size and function.
5.3.6 Subcellular location(s) of insert(s) (e.g. nucleus, chloroplasts, mitochondria, or maintained in non-integrated form), and methods for determination of the location of the insert(s).
5.3.7 The molecular characterisation of the inserted nucleic acid sequence(s) at the insertion site(s).

5.4 Provide a description of the methods used to produce the GMO.

5.5 Describe the nature and source of any vector(s) used for production of the GMO. Provide information on the potential for mobilisation or transfer of the vector(s) to other organisms.

5.6 Provide detailed information on the recombinant vector construct(s), including the region of the vector intended for insertion, promoter(s) for expression of the inserted nucleic acid(s), reporter gene(s), and antibiotic resistance gene(s).

5.7 Provide information on the expression of the inserted nucleic acid sequence(s) in the GMO:

5.7.1 Provide information on the rate and/or level of expression of the inserted nucleic acid sequence(s) or inserted gene(s) and the sensitivity of the method of measurement of the rate and level.
5.7.2 State whether expression is constitutive or inducible.
5.7.3 Provide information on the part(s) and/or organ(s) of the GMO, or organ(s) of a host organism to which the GMO is administered, where the inserted sequence(s) or inserted gene(s) are expressed or expression product(s) are targeted.

5.8 Provide detailed protocols for the specific detection of the GMO in the application. Provide information on the sensitivity, reliability and specificity of the techniques for detection.

5.9 Provide information on how the GMO differs, or is expected to differ, from the host or unmodified recipient organism in regard to:

5.9.1 General traits.
5.9.2 Natural habitat and geographic distribution.
5.9.3 Reproduction.
5.9.4 Dissemination/dispersion, including persistence and invasiveness.
5.9.5 Survivability, especially in the spectrum of conditions which are likely to be found in the proposed release area(s) and surrounding environments(s).
5.9.6 The ability of the GMO to transfer genetic material to other organisms, including bacteria and plants.
5.9.7 Adverse effects on:

5.9.7.1 Humans
5.9.7.2 Animals
5.9.7.3 Plants
5.9.7.4 Agricultural production
5.9.7.5 Any other aspect of the environment
5.9.7.6 Other.

6. BRIEF SUMMARY OF FIELD OR CLINICAL TRIALS UNDERTAKEN THUS FAR

6.1 Submit a list of previously authorised field or clinical trials undertaken by the applicant with the GMO in:

6.1.1 South Africa

6.1.2 Other countries

6.1.3 Include information on the country, year, location and the authority from which permission was obtained to run the field or clinical trials. Provide documentation from the body controlling the release.

6.2 Provide a scientific summary of the field performance or clinical trial performance of the GMO, including: (i) a scientific explanation of the efficacy of the introduced trait(s) for each of the previously authorised field trials listed in 6.1, or (ii) the outcome of each of the previously authorised clinical trial(s) listed in 6.1. Discuss any factors that might suggest a greater, or a lesser, risk for adverse consequences for the now-proposed trial release?

(Provide references or reports to support your statements).

7. TRIAL RELEASE: GENERAL INFORMATION

7.1 Trial site location:

7.1.1 What is the location of the proposed field or clinical trial release site(s)?

7.2 What quantity of the GMO is to be released, and what are the arrangements for producing the GMO in the quantities required for the field trial.

7.3 What are the arrangements for transporting the GMO to the release site?

7.4 What is the desired duration of the field or clinical trial and the reason for the desired duration?

7.5 Provide details of the experimental design for the field trial or clinical trial.

8. ENVIRONMENTAL IMPACT AND PROTECTION

8.1 What evidence is there concerning the transferability of the inserted nucleic acid sequences to other organisms in the release site and surrounding environment? If transferable, provide information to which organisms and at what frequencies the inserted nucleic acid sequences is transferable?

8.2 What evidence is there concerning the likelihood of spread/dissemination of the GMO outside of the release site or host organism?

8.3 What data are available to suggest that the introduced nucleic acid sequences have no deleterious effect in the long term upon the species into which it has been introduced or to related species or any other organisms or to the environment in general?

8.4 Is the GMO intended to modify the characteristics or abundance of other species? If so, what are the target species and intended consequences?

8.5 Detail any effects, especially long-term, that the trial release of the GMO is likely to have on the biotic and abiotic components of the environment. The answer should consider effects on general ecology, ecosystems, biodiversity, environmental quality, pollution in the area, non-target organisms, human/animal/plant health, and genetic resources (e.g. susceptibility of economically important species to biocides).

8.6 What are the consequences of the GMO remaining in the environment beyond the planned period?

9. HUMAN AND ANIMAL HEALTH AND PATHOGENICITY

9.1 Will the GMO or its products enter the human or animal food chains as part of the field or clinical trial experiments? If no, what measures will be taken to prevent human or animal ingestion of the GMO (if relevant)? If yes;

9.1.1 Provide information on the toxicity to humans and animals of the newly expressed protein(s) (including any marker proteins) or new constituents other than proteins.

9.1.2 Provide information on the allergenicity to humans and animals of the newly expressed protein(s) (including any marker proteins).

9.2 What are the implications of the proposed trial release activity with regard to the health and safety of the workers, cleaning personnel and any other person that will be directly or indirectly involved in the activity? Please take into consideration the provisions of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993 as amended by Act No. 181 of 1993) (and accompanying regulations) and indicate the proposed health and safety measures that would be applied.

10. MONITORING AND RISK MANAGEMENT PLAN

10.1 Please specify a supervision / monitoring and risk management plan (approach, strategy, method and analysis) that would be implemented for the trial release. The plan should include information on arrangements for storing the GMO in preparation for the trial release, for handling the GMO during the trial release, and for the monitoring of potential hazardous or deleterious effects that may result from the trial release of the GMO.

10.2 Indicate any contingency plans and emergency procedures that will be applied in the event of an accident or to deal with extreme conditions such as storms, floods, and fires during the course of the trial release.

10.3 Please specify the provisions to remove the GMO from the test site or any other place where it may be found upon completion of the trial release and to restore the test site and any such other place to its original form.

11. COMPLETE THE AFFIDAVIT. The affidavit is an inseparable part of the application form.

PART II (the section relevant to the GMO should be completed)

Section A: Trial release: GM crops or pasture plants

1. Provide information on how the GM plant differs from the recipient organism in general agronomic traits.

2. Reproduction and sexually compatible species:

2.1 For pollen spread, identify pollinating agents and the distances to which pollen is known to spread from the GM plant.

2.2 Provide details (including their distribution and proximity to trial release areas) on cultivated species that may become cross-pollinated with the GM pollen.

2.3 Give details (including their distribution and proximity to trial release areas) of wild or indigenous species that may become cross-pollinated with the GM pollen.

2.4 In the case of vegetative reproduction, describe methods to be used to limit vegetative spread of the GM plant into the environment.

2.5 How do seeds of the GM plant interact in the environment and what long-term effects will the seed likely have on the environment?

3. If the foreign genes give rise to crops tolerant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.

4. Trial location:

4.1 Provide one or more recent maps (aerial photo or orthophoto) at the appropriate scale with the trial site(s) marked.

4.2 Provide a description of each field trial site in terms of:

5.2.1 Size
5.2.2 Soil
5.2.3 Groundwater level
5.2.4 Topography
5.2.5 Flora and fauna, with special consideration of threatened or endangered species
5.2.6 Climate, especially prevailing winds
5.2.7 Former use and history of the site
5.2.8 Distance from the nearest human settlements, along with the size of such settlements
5.2.9 Distance from surface waters, and
5.2.10 Distance from listed ecosystems, critical biodiversity areas, and protected areas. In addressing this section, the Biodiversity GIS (BGIS) website (http://bgis.sanbi.org/news.asp#newtools) may be of use.

5.3 Provide a description of the environment immediately surrounding the trial release site. In addition, provide a map indicating the trial site and the location of, and distance to, nearby (within 3 km) structures (e.g. fences, roads, and buildings), landmarks, and crops.

5.4 Describe the barriers planned in order to segregate the experiments comprising the trial release from the surrounding environment.

Section B: Trial release: GMO vaccines

1. Provide details on the pathogenicity of the GMO vaccine, including evidence from the use of the host vaccine organism or other GMOs having the same host vaccine organism in present vaccines either in use or under development.

2. Based on data obtained in contained experiments (please supply experimental data or references), what are the effects expected when the GMO vaccine interacts with non-target species?

3. In the case of human clinical trials, what is the likelihood that the live GMO vaccine may infect immunocompromised individuals in the population and how pathogenic would the GMO vaccine be in such individuals?

4. Provide details on safety and tolerability studies undertaken on the GMO vaccine, including toxicology and biodistribution.

5. Provide details on allergenicity / hypersensitivity studies undertaken on the GMO vaccine.

6. What is the existing evidence regarding level and duration of immunity produced by the GMO vaccine in the target species?

7. In the case of a human clinical trial, provide details on any pre-clinical studies undertaken with the GMO vaccine.

8. Provide details on the planned adverse events monitoring to be undertaken during the trial release.

9. Provide details on the likelihood of integration of the GMO vaccine into the vaccinees' DNA.

10. Will the subjects carry live GMO vaccine at the end of the trial? If so, will they be likely to disseminate the live GMO vaccine to the general population?

11. Are any challenge tests or other tests using virulent field strains to be carried out on vaccinated animals? If yes, provide details of the tests.

12. Would the use of this GMO vaccine preclude the future use of the host vaccine organism for immunisation purposes?

13. What is the likelihood that any component of the GMO vaccine or the host vaccine organism would be used in other human or animal vaccines?

14. How will you distinguish between the GMO and the GMO donor and recipient wild type organisms?

15. What arrangements are proposed to dispose of waste containing any GMO vaccine either during the trial release or once the trial release is completed?

PART III (to be completed for all GMOs)

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:	<Text entry>
3.	Contact details:	<Standard contact address details: name, function (job title/designation), organization, address, phone, fax, email, website>
	LMO information	
4.	Name and identity of the living modified organism:	<Text entry – Identity of the living modified organism, and the differences between the biological characteristic of living modified organism and those of the recipient organism or parental organisms>
5.	Unique identification of the living modified organism:	<Text entry>
6.	Transformation event:	<Text entry>

7.	Introduced or Modified Traits:	Choose the trait from the following list: <u>A. Abiotic environmental tolerance</u> - Altered photoperiod sensitivity - Cold or heat tolerance - Drought or water tolerance - Other abiotic environmental tolerance <u>B. Altered growth, development and product quality</u> - Altered ripening or flowering - Colouration - Fertility restoration - Growth rate or yield - Male sterility - Nutritional composition (incl. allergenicity) - Other growth, development and product quality - Selectable marker genes and reporter genes - Uptake or degradation of environmental pollutants **Chemical tolerance** - Herbicide tolerance - Other chemical tolerance **Medical products** - Animal vaccines - Development of transplant organs - Other medical products - Production of pharmaceuticals **Pest resistance** - Bacterial resistance - Fungus resistance - Insect resistance - Nematode resistance - Other pest resistance - Virus resistance and <text entry for other, not on the list>
8.	Techniques used for modification:	<Controlled vocabulary for common techniques - Please select techniques used for the transformation: plasmid carried by *Agrobacterium tumefaciens*, biolistic methods, breeding, electric shock (poration), osmotic shock> *and* <text entry – for other, not on the list>
9.	Description of gene modification:	<Text entry>
		Characteristics of modification
10.	Vector characteristics (Annex III.9(c)):	<Text entry - Characteristics of the vector, should include its identity, if any, and its source or origin, and its host range >
11.	Insert or inserts (Annex III.9(d)):	<Text entry - Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced>

Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	<Controlled vocabulary: agreed international standards> *and* <text entry – for other, not on the list>
13. Common name of recipient organism or parental organisms:	<Controlled vocabulary with thesaurus> *and* <text entry – for other, not on the list>
14. Point of collection or acquisition of recipient or parental organisms:	<Text entry >
15. Characteristics of recipient organism or parental organisms related to biosafety:	<Text entry >
16. Centre(s) of origin of recipient organism or parental organisms:	<Text entry - Describe the exact location and give geographical coordinates>
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	<Text entry - Describe the exact location and give geographical coordinates>
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	<Text entry - Description of the habitat where the organisms may persist or proliferate>
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<Controlled vocabulary: agreed international standards> and <text entry for other, not on the list>
20. Common name of donor organism(s):	<Controlled vocabulary with thesaurus> and <text entry for other, not on the list>
21. Point of collection or acquisition of donor organism(s):	<Text entry - the exact location and geographical coordinates>
22. Characteristics of donor organism(s) related to biosafety:	<Text entry - Relevant biological characteristics of donor organisms>

Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	<Text entry - Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms>
24. Receiving environment (Annex III.9(h)):	<Text entry - Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment>
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	<Text entry - Suggested detection and identification methods and their specificity, sensitivity and reliability>
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<Text entry - An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism>
27. Evaluation of the consequences (Annex III.8(c)):	<Text entry - An evaluation of the consequences should these adverse effects be realized>
28. Overall risk (Annex III.8(d)):	<Text entry - An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized>
29. Recommendation (Annex III.8(e)):	<Text entry - A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks>
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	<Text entry - details about any further information that has been requested where there is uncertainty regarding the level of risk, as well as any information on risk management strategies and/or monitoring of the LMO in the receiving environment>
Additional information	
31. Availability of detailed risk assessment information:	<Text entry - Please indicate whether more details on the risk assessment are available and how they can be accessed>
32. Any other relevant information:	< Text entry - any other information that is relevant to the risk assessment. e.g. information of non CBI nature that was included in the original application but is not included in this form>
33. Attach document:	*Not applicable to applicant*<Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server>
34. Notes:	<Text entry>

AFFIDAVIT/STATEMENT

(to be completed in the presence of a Commissioner of Oaths)

I…….

ID Number……. Age ……..

Residing address …….

Working address ……..

Tel ……..(w) ……(h) ……(cell)

Declare under oath in English / confirm in English –

……
……
……
……

I am familiar with, and understand the contents of this declaration. I have no objection/have objection to taking the prescribed oath. I consider the prescribed oath as binding to my conscience.

Place: …….. Date: ……..

Time: ……

Signature: ……

I certify that the above statement was taken from me and that the deponent has acknowledge that he/she knows and understands the contents of the statement. The statement was sworn to/affirmed before me and deponents signature/mark/thumb print was placed thereon in my presence.

At: …… on …… at …….

……..
Commissioner of Oaths
(details to be provided on physical and postal address e.g. stamp of police station)

……
Force number/Rank/Name – print

Directions for the applicant:

(This page must be excluded from the documents submitted to the Registrar's office)

- Please complete all relevant sections of the questionnaire CLEARLY.
- Please provide 1 original and 15 copies of the application with confidential information for use by the regulatory bodies appointed in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

  Please confirm with the Office of the Registrar with regard to submission of electronic applications.
- Please provide an additional hard copy and electronic version of the application containing no confidential information. Non-Confidential Business Information (Non-CBI) copy is the application where any information that is regarded as confidential business information has been deleted. Please take note that a reference to the specific section of the Promotion of Access to Information Act, 2000 must be made whenever you "delete" information in this application. This copy must be clearly marked NON-CONFIDENTIAL, and will be made available for public scrutiny and placed on the website of the Department. This copy of the application must be submitted to the Registrar one day after the placing of the public notices.
- Please provide an electronic and hard copy of a risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed in Part III of this document.
- Please conduct a public notification in accordance with Regulation 6 of the GMO Act, and making use of the guideline document available on the website of the department. Copies of the public notification must be submitted with the application.
- Please submit all relevant documentation to the Registrar at the address indicated in the application form.
- The appropriate fee stipulated under the GMO Act must accompany the application. Please note that the Registrar's office does not accept cash.