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

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

PART I

1. NAME AND ADDRESS OF APPLICANT

2. BRIEF DESCRIPTION OF PROPOSED TRIAL RELEASE

3. OBJECTIVE

3.1 What is the aim of the proposed trial release of the genetically modified organism (GMO)? What are the benefits of this approach compared with other possible methods, especially those not involving planned release?

3.2 Should the trial release prove to be successful, is it intended that a general release of the GMO be proposed? If so:

3.2.1 When is it proposed that the general release take place?

3.2.2 Where is it proposed that the general release take place?

3.2.3 Who is proposing that the GMO be released?

3.3 Is it intended that the GMO and/or its derivative(s) be marketed in the Republic of South Africa?

4. NATURE OF ORGANISM AND NOVEL GENETIC MATERIAL

4.1 What is the species of the GMO to be released?

4.2 Is it known whether the unmodified form(s) have any adverse effect on:-

4.2.1 Humans, animals or plants;

4.2.2 Agricultural production; and

4.2.3 Any other aspect of the environment

4.3 Furnish a description of the genetic and resultant phenotypic modifications of the GMO. This should include the origin of the inserted DNA, the procedure used to induce the genetic modification and the extent to which it has been characterised.

4.4 What is the frequency of reversion, i.e. loss of genetic modification?

4.5 As what will the GMO be known – identification name?

4.6 How do you verify that you have the desired GMO?

4.7 What methods are to be used to test for batch to batch consistency?

4.8 On the basis of contained experiments describe:-

4.8.1 The survival rates of the GMO in the spectrum of conditions which are likely to be found in the proposed release area(s) and surrounding environments(s);

4.8.2 The capability of the GMO to disperse from the release area and the dispersal mechanisms; and

4.8.3 Any other relevant information.

(Where reports or publications are available for any of the above information, please furnish copies or references).

4.9 Should the Advisory Committee at any stage in the future need to ascertain whether the GMO is the same as the GMO specified here, how can this be done?

4.10 Provide a protocol and materials to enable detection of foreign gene(s) in surrounding microbial, plant or animal life.

5. TRIAL RELEASE: GENERAL

5.1 Full details are required as to the manner in which the trial release of the GMO is to be undertaken. The following aspects, at least, should be addressed:-

5.1.1 The location of the site for the proposed released (e.g. Ordnance survey map of appropriate scale with site marked, as well as a map indicating crops planted adjacent to the site and the distances involved); including digital maps indicating the surrounding area with appropriate legends and scale conversions

5.1.2 Indicate the detailed experimental designed to be applied in the trial; also indicate whether randomised design or randomised block design

5.1.3 Description of the test site in terms of –

- Size
- Soil
- Groundwater level
- Topography
- Flora and fauna
- Climate, especially prevailing winds
- Former use
- Distance from the nearest human settlements, along with the size of such settlements
- Distance from surface waters
- Distance from environmentally and otherwise protected areas;
- History of the site

5.1.4 Description of the environment immediately surrounding the release site;

5.1.5 The barriers planned in order to segregate the experiments comprising the trial release from the surrounding environment;

5.1.6 The supervision and monitoring of the trial release

5.1.7 The contingency plans to deal with extreme conditions such as storms, floods and bush fires during the course of the trial release;

5.1.8 The provisions to remove or eliminate 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;

5.1.9 The arrangements for producing the GMO in quantity;

5.1.10 The arrangements for transporting the GMO to the release site; and

5.1.11 The quantity of the GMO to be released.

5.2 What potential hazardous or deleterious effects resulting from the trial release of the GMO can be postulated?

5.2.1 Which of these effects are to be monitored and evaluated during the trial?

5.2.2 How are these effects to be monitored and evaluated during the trial?

5.2.3 If some effects are not going to be monitored, why not?

5.3 Have similar releases of similar GMO been made before, either within or outside South Africa? If so:-

5.3.1 What were the beneficial consequences?

5.3.2 What were the adverse consequences?

5.3.3 What factors 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).

5.4 Have similar requests or applications for the release of this particular GMO been made before? If so:-

5.4.1 Where was the application made?

5.4.2 What was the result?

5.5 What evidence is there concerning the transferability of the inserted genetic trait to other organisms in the release site and surrounding environment? If transferable:-

5.5.1 To which organisms; and

5.5.2 At what frequencies is it transferable?

5.6 What data are available to suggest that the introduced genetic trait has no deleterious effect in the long term upon the species into which it has been introduced or related species or any other organisms or the environment in general?

5.7 Is the GMO intended to modify the characteristics or abundance of other species? If so, what are:-

5.7.1 The target species; and

5.7.2 The intended consequences?

5.8 What experimental results or information are there to show the probable consequences (positive and negative), of the release of such a modified organism, including impacts on:-

5.8.1 Human, animal or plant health;

5.8.2 Agricultural production;

5.8.3 The target and non-target organisms in the area;

5.8.4 The general ecology, environmental quality and pollution in the area; and

5.8.5 Genetic resources (e.g. susceptibility of economically important species to herbicides, pesticides etc)?

What is your assessment of the possible effects?

5.9 Are there any unlikely but possible impacts due to the trial release? If so:-

5.9.1 Would any of these have substantial impacts if they actually occurred?

5.9.2 Does the release protocol monitor these low probability risks?

5.9.3 How will these risks be monitored?

5.10 What are the consequences of the organism remaining in the environment beyond the planned period? (Cover the same range of issues as set out in 5.7 and 5.8 above).

5.11 Has a trial release been carried out in the country of origin of the GMO or a GMO with similar characteristics

5.11.1 If so, what was the outcome? (Provide documentation from the body controlling the release).

5.11.2 If not, provide reasons why the trial release was not carried out.

5.12 What are the implications of the proposed 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. 181 of 1993) and accompanied regulations.

5.13 Indicate the proposed health and safety measures that would be applied to safeguard employees during the proposed activity.

5.14 Provide a copy of a press release informing the public of the trial release of the GMO. Please submit proof that the notice has been published in at least three newspapers circulating the area in which the proposed release is to take place.

6. TRIAL RELEASE: VACCINES

6.1 For human clinical trials, what arrangements are proposed to dispose of waste containing any vaccine organisms?

6.2 Will the subjects carry live vaccine organisms at the end of the trial? If so,

6.2.1 Will they be likely to disseminate the live vaccine organisms to the general population?

6.3 Based on data obtained in contained experiments (please supply), what are the effects expected when the vaccine organism interacts with target and non-target species in the test area and surrounding environment?

6.4 What is the existing evidence regarding level and duration of immunity produced in the target species?

6.5 What challenge or other tests using virulent field strains are to be carried out on vaccinated animals?

6.6 What is the likelihood that the host vaccine organism would be used in other human or animal vaccines?

6.7 Would the use of this vaccine preclude the future use of the host vaccine organism for immunisation purposes?

6.8 How will you distinguish between the GMO and the wild type organism?

7. TRIAL RELEASE: MICRO-ORGANISMS ASSOCIATED WITH PLANTS

7.1 What is the target species of plant?

7.2 Is the organism able to establish itself on/in non-target species in the surrounding environment?

7.3 To what extent does the organism survive and reproduce on/in:-

7.3.1 The target plant;

7.3.2 The rhizosphere of the target plant species;

7.3.3 Other plant species in the test site; and

7.3.4 The surrounding environment.

7.4 What characteristics do you intend to impart to the target plant species?

7.5 Can these characteristics be imparted to non-target plant species, especially those in the surrounding environment? If so:-

7.5.1 Is the distribution and abundance of any non-target plant species likely to be affected by the acquisition of these characteristics?

7.6 In the case of soil organisms, what are the effects on organisms likely to be in the test area which is known to be beneficial to plants (e.g. Rhizobium, Frankia and mycorrhizal fungi)?

7.7 In the case of soil organisms, what are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, and nutrient levels)?

7.8 How will one distinguish between the GMO and the wild type organism?

8. TRIAL RELEASE: MICRO-ORGANISMS ASSOCIATED WITH ANIMALS (e.g. ruminants)

8.1 What is the target species of animal?

8.2 What is known about the organism's ability to survive and reproduce?

8.3 Is the organism able to establish itself in non-target species?

8.4 What characteristics do you intend to impart to the target species of animal (e.g. ability to degrade pasture toxins)?

8.5 Can these characteristics be imparted to non-target animal species? If so:-

8.5.1 are the distribution and abundance of non-target species likely to be affected by the acquisition of these characteristics?

8.6 In the case of farmed target species, can these characteristics be imparted to feral populations of the target species? If so:-

8.6.1 Are the distribution and abundance of such feral populations of the target species likely to be affected by the acquisition of these characteristics?

9. TRIAL RELEASE: MICRO-ORGANISMS TO BE USED FOR MODIFYING THE ENVIRONMENT (e.g. biological control, pollution control)

9.1 In the case of biological control organisms, what is the biological control target species?

9.2 What direct effects do the unmodified and modified organisms have on:-

9.2.1 The target species;

9.2.2 Non-target species (including humans); and

9.2.3 Any plant or animal species being protected from the target species?

9.3 What is known about the organism's ability to survive and reproduce in association with the target species or substance?

9.4 Can the organism establish itself in association with non-target species or substances?

9.5 Does the organism produce metabolites, which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain?

9.6 Can the modified genetic traits be transmitted to other micro-organisms, which are likely to be in the environment? If so:-

9.6.1 Are these likely to affect non-target species or substances?

9.7 What genetic response might be invoked in populations of the target organism as a result of the use of the modified organism (e.g. increased resistance to the modified organism)?

10. MICRO-ORGANISMS TO BE USED IN FOOD

10.1 What relationship does the micro-organism or the introduced DNA have to known human pathogens?

10.2 What is the possibility that the micro-organism will produce metabolites, which may have deleterious effects?

11. DOMESTICATED OR FARM ANIMALS

11.1 Will the animals in this experiment be allowed to breed?

11.1.1 If not, is breeding planned for later experiments?

11.1.2 If so, are the arrangements for handling any offspring the same as those for the experimental animals? If not:

11.1.3 Please specify the arrangements.

11.2 What are the desirable effects expected to result from the use of the modified animal (e.g. improved reproduction, weight gain, disease resistance, production gains etc)?

11.3 What undesirable effects may result from the release (e.g. difficult birth, reduced fertility, increased disease prevalence, tumourgenicity, production losses etc)?

11.4 Are any of the likely gains directly linked to losses in other characteristics of the species (e.g. an increased growth rate being accompanied by a decrease in wool or milk production)?

11.5 Can the genetic trait be transmitted by means other than normal reproduction?

11.6 Do feral populations of the species exist in South Africa? If so:-

11.6.1 Do the feral populations cause agricultural, environmental or disease-control problems?

11.6.2 Specify the problems.

11.7 Has any experimental work been done on the phenotypic expression of the novel genetic material in feral genomes (e.g. cross-breeding of modified animals with captive feral animals)? If so:-

11.7.1 What were the results?

11.8 What is the likelihood of the novel genetic material entering the feral gene pool (e.g. by interbreeding with modified farm animals)?

11.9 Would the entry of the novel genetic material into a feral gene pool have any effect on:-

11.9.1 The distribution and abundance of the feral population

11.9.2 Its ability to cause agricultural, environmental or disease-control problems?

11.10 If no feral populations exist in South Africa, would the imparted characteristics enhance the ability of the species to establish feral populations?

12. CROP OR PASTURE PLANTS

12.1 Will the plants in this experiment be allowed to set seed?

12.1.1 If not, is this planned for later experiments?

12.2 Is vegetative propagation planned?

12.3 What are the desirable effects expected to result from the use of the modified plant (e.g. increased production, improved quality of product, new product, disease, insect or herbicide resistance etc)?

12.4 What undesirable effects may result from the release (e.g. reduced fertility, increased disease prevalence, production losses etc)?

12.5 Are any of the likely gains directly linked to losses in other characteristics of the species?

12.6 Are any members of the genus of modified plants known to be weeds?

12.7 Can the genetic trait be transmitted by means other than by normal reproduction?

12.8 Does the imparted characteristic have the potential to add or subtract substances from the soil (e.g. nitrogen)?

12.9 Has the modified plant been shown to be non-toxic to animals and humans?

12.10 Could any toxic products concentrate in the natural or human food chain?

12.11 Having regard to the pollination characteristics of the species, do wild populations of the species, or related species with which it can interbreed, exist in the vicinity of the field trial or agricultural site?

12.11.1 If so, have any experiments been conducted to test the phenotypic expression of the novel genetic material in the wild form or the related species?

12.12 Having regard to the pollination characteristics of the plant, what is the likelihood of the novel genetic material entering a pre-existing gene pool? Provide information on the pollinators specific to the crop and the measures to be taken to prevent pollen spread to unmodified plants.

12.13 Should the imparted characteristic (e.g. insect, herbicide or disease resistance) “escape” into a wild population, would it have the potential to affect the distribution and abundance of that population?

12.14 Would there be any consequent problems with respect to:-

12.14.1 Agriculture;

12.14.2 The environment; and

12.14.3 Disease control?

12.15 If there is any possibility of 12.12 and/or 12.13 occurring, has any attempt been made to minimise the risk (e.g. by imparting male sterility)?

12.16 Could the imparted characteristic (either in the cultivation or in a wild population) provoke a genetic response in populations of other species (e.g. increase the resistance of an insect population to an insecticide)?

13. MONITORING AND ACCIDENTS

13.1 Indicate the methods and plans for monitoring of the GMO in a comprehensive compliance plan

13.2 Indicate any emergency procedures that will be applied in the event of an accident in a comprehensive contingency plan

14. PATHOGENIC AND ECOLOGICAL IMPACTS

14.1 Submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts.

15. RISK MANAGEMENT

15.1 Please indicate any risk management measures that would be required during the trial.

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

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 13 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 provide an additional hard copy and electronic version of the application containing no confidential information. **Non-Confidential Business Information copy (NON-CBI copy) - this is your application where you have deleted any information that you regard as confidential business information. Please take note that you must make reference to the specific section of the Promotion of Access to Information Act, 2000 whenever you "delete" information in this application** This copy must be clearly marked: NON-CONFIDENTIAL, and will be made available for public scrutiny.. This copy of the application must be submitted to the Registrar one day after placing of the public notices.
- Please provide an electronic copy of both the non-confidential application and risk assessment and in additional include a hard copy of the risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed below.
- 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 return your completed questionnaire to the Registrar at the address indicated in the application form.
- Proof of payment of the appropriate fee stipulated under the GMO Act must accompany the application. Please note that the Registrar's office does not accept cash.

COMMON FORMAT FOR Risk Assessment
(In accordance with Annex III of the Cartagena Protocol ion 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: A. <u>Abiotic environmental tolerance</u> - Altered photoperiod sensitivity - Cold or heat tolerance - Drought or water tolerance - Other abiotic environmental tolerance B. <u>Altered growth, development and product quality</u> - Altered ripening or flowering - Coloration - Fertility restoration - Growth rate or yield - Male sterility - Nutritional composition (inc. 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. Centre(s) 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 centre(s) 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

(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 –

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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