agriculture, land reform & rural development
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Agriculture, Land Reform and Rural Development
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

Notes:

1. Host or unmodified organism refers to an organism prior to the genetic modification(s) that results in the organism being classified as a GMO.
2. Applicants should substantiate “yes” or “no” answers and provide answers that are detailed enough to enable thorough risk assessment by regulatory bodies. Answers may, where appropriate, be summaries that are based on relevant, peer-reviewed literature.
3. Applications with superficial answers may result in significant delays in the review and decision-making process.
4. The application is structured in two tiers:
    a. Tier 1. Part I to III of Tier 1 must be completed for all GMOs.
    b. Tier 2. Sections in Part IV only need to be completed if the applicant is referred to these sections based on the applicant’s responses in Tier 1. In Part V, only the section relevant to the GMO should be completed.
5. Part VI must be completed for all GMOs.
6. Figure 1 on page 2 shows a graphical overview of the key parts of the application template, with colour coding used to assist applicants in understanding which parts of the application template they need to complete.
7. Complete the affidavit. The affidavit is an inseparable part of the application form.

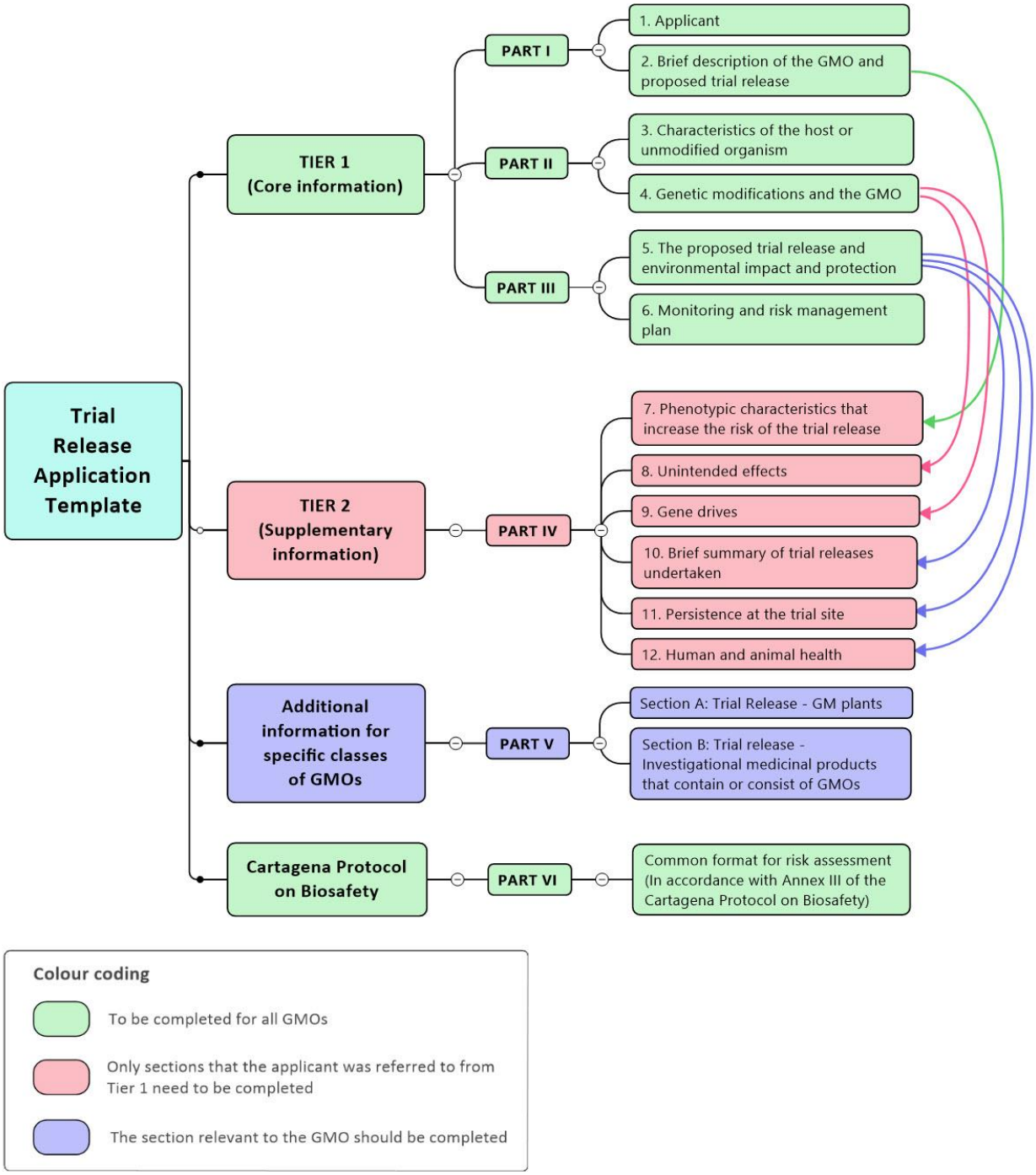

Figure 1. Graphical overview of the two-tier trial release application template. The colour coding shows which parts need to be completed by the applicant: (1) Tier 1 and the Cartagena Protocol on Biosafety sections need to be completed for all GMOs, (2) for Tier 2, sections in Part IV only need to be completed if the applicant is referred to these sections based on the applicant's responses in Tier 1, and (3) in the "Additional information for specific classes of GMOs" part of the template, only the section relevant to the GMO should be completed. The arrows show where in the application template an applicant may be referred from Tier 1 (core information) to Tier 2 (supplementary information).

TIER 1 (Core Information)

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 AND PROPOSED TRIAL RELEASE

2.1 Provide a unique identifier and brief description of the GMO, the intended function(s) of the genetic modification(s), and the genetically modified trait(s) of the GMO.

2.2 Provide a brief description of the proposed trial release.

2.3 Is the unmodified organism indigenous to South Africa or does it have a history of safe use in South Africa?

2.4 Does the genetic modification(s) result in changes in the unmodified organism in terms of the following?

(If the answer is yes for any one of the characteristics below, complete section 7 of Part IV of the application)

2.4.1 Increased weediness

2.4.2 Increased risk of gene flow

2.4.3 Increased pest potential

2.4.4 Increased pathogenicity or host range

2.4.5 Increased persistence in the environment

2.4.6 Adverse impacts on non-target organisms

2.5 Is the GMO able to reproduce in the environment?

PART II (to be completed for all GMOs)

3. CHARACTERISTICS OF THE HOST OR UNMODIFIED ORGANISM

3.1 Specific and common names of the unmodified organism.

3.2 Describe the natural habitat, geographic distribution, geographic origin, and centres for diversity of the unmodified organism. Also, provide details on the type of environment and the geographical areas for which the unmodified organism is suited.

3.3 Comment on whether or not the unmodified organism has any adverse effect on:

3.3.1 Humans

3.3.2 Animals

3.3.3 Plants

3.3.4 Agricultural production

3.3.5 Any other aspect of the environment

3.4 Reproduction of the unmodified organism:

3.4.1 Provide detailed information on the mode(s) of reproduction.

3.4.2 Provide detailed information on specific factors affecting reproduction.

3.4.3 Provide detailed information on the generation time.

3.5 Survivability in the environment of the unmodified organism:

3.5.1 Provide details on structures produced by the unmodified organism for survival or dormancy.

3.5.2 Provide information on specific factors affecting survivability of the unmodified organism in the environment.

3.6 Dissemination of the unmodified organism in the environment:

3.6.1 Provide details on how the unmodified organism may disseminate in the environment.

3.6.2 Provide information on specific factors affecting dissemination of the unmodified organism in the environment.

3.7 Provide information on how the unmodified organism is usually utilised in agriculture, forestry, medicine, or other areas.

4. GENETIC MODIFICATIONS AND THE GMO

4.1 Was a donor organism(s) used as a source of the nucleic acid sequences used in the genetic modification(s)? If yes, provide:

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

4.1.2 Provide details of the natural habitat, geographic distribution, geographic origin, and centres for diversity of the donor organism(s).

4.2 Provide a detailed description of the methods used for the genetic modification(s) and, in cases where vectors were used, describe the nature and source of the vectors used.

4.3 Provide detailed information on the genetic construct that enacts the genetic modification in the unmodified organism, including the source of donor DNA and the size and intended function of each constituent

fragment that is inserted in the host's genome or that plays a role in making the genetic modification(s). Use maps and tables as appropriate.

4.4 Provide detailed information on the genetic modification(s) (e.g., base edits, inserted or deleted sequences) and phenotypic trait(s) and characteristics associated with the genetic modifications.

All information provided must be substantiated with appropriate empirical evidence and a description of the methodology used to generate the evidence.

There is no prescribed way for presenting the information, but information should be presented in a way that facilitates thorough review and must include the following:

(a) Identification and location of all inserted sequences (including short indels) and genes, including the copy numbers for all inserts, both complete and partial. The organisation of the inserted genetic material at the insertion site.

(b) Identification and location of all deleted sequence(s), the size of the deleted region(s), and the gene(s) and function(s) that are impacted upon by the deletion(s).

(c) The identification and location of all nucleotide base edits that are part of the planned genetic modification(s).

(d) The molecular methods used for determination of the location(s) of the genetic modification(s) and copy number determinations. The location(s) of genetic modification(s) information should indicate if the modification(s) is in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form.

(e) The genetic stability of the modification(s) and the methods used to assess the stability.

(f) The expression of the inserted sequences or genes, including whether expression is constitutive or inducible. In the case of inducible expression, discuss the induction conditions.

(g) The expression of previously inactive genes or changes in the expression of endogenous genes intentionally brought about by genetic modification(s) in the GMO.

(h) The biological activity, trait and phenotypic outcome associated with each genetic modification in the GMO.

(i) The biological activities, traits and phenotypic outcomes that results from the combination of genetic modifications in the GMO.

(j) The phenotypic stability of the GMO.

4.5 Provide information on how the GMO differs, or is expected to differ, from the unmodified organism with regard to:

4.5.1 General traits (including agronomic traits were relevant).

4.5.2 Natural habitat and geographic distribution.

4.5.3 Reproduction.

4.5.4 Dissemination/dispersion, including persistence and invasiveness.

4.5.5 Survivability, especially in the spectrum of conditions which are likely to be found in the proposed release area(s) and surrounding environments(s).

4.5.6 The ability to transfer genetic material to other organisms, including bacteria and plants.

4.5.7 Adverse effects on:

4.5.7.1 Humans

4.5.7.2 Animals

4.5.7.3 Plants

4.5.7.4 Agricultural production

4.5.7.5 Any other aspect of the environment

4.5.7.6 Other.

4.6 Provide information on the assessment of unintended effects in the GMO (e.g., off-target effects, unintended DNA insertions, and chromosomal rearrangements). Include details of the assessment methods. If there are unintended effects, complete section 8 of Part IV of the application.

4.7 Is the genetic modification designed to spread through a population at higher-than-normal rates of inheritance? If yes, complete section 9 of Part IV of the application.

4.8 Provide detailed, implementable protocols or standard operating procedures (SOPs) for:

4.8.1 The detection in the environment/other organisms of the genetically modified nucleic acid sequences that define the organism as a GMO.

4.8.2 Identification and detection of the GMO in the environment and for distinguishing between the GMO and the unmodified organism.

The responses for 4.8.1 and 4.8.2 should include information on the sensitivity, reliability and specificity of the techniques.

The detailed protocols or SOPs should be included as annexures to the application.

PART III (to be completed for all GMOs)

5. THE PROPOSED TRIAL RELEASE AND ENVIRONMENTAL IMPACT AND PROTECTION

5.1 Have previously authorised field or clinical trials with the GMO been undertaken in South African or other countries. If yes, refer to section 10 of Part IV of the application.

5.2 Provide a description of the proposed trial release, including an overview of the objectives and experimental design.

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

5.4 Trial site description and environmental impact and protection:

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

5.4.2 Briefly describe the trial site(s), including the trial site size(s), and the quantity of the GMO to be released per trial site.

5.4.3 What evidence is there concerning the likelihood of spread/dissemination of the GMO outside of the release site or, in the case of GMO investigational medicinal products (such as GMO vaccines), the treated or vaccinated humans or animals?

5.4.4 What evidence is there concerning the transferability of the GMO's nucleic acid sequences, particularly sequences that define the organism as a GMO, to other organisms in the trial release site and surrounding environment? If transferable, provide information to which organisms and the likelihood of transfer.

5.4.5 Describe the methods and measures to be used to:

5.4.5.1 Contain the GMO within the trial site.

5.4.5.2 Prevent the transfer of the GMO's nucleic acid sequences, particularly sequences that define the organism as a GMO, to other organisms in the release site and surrounding environment.

5.4.6 What data are available to suggest that the genetic modifications or nucleic acid sequences that define the organism as a GMO 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?

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

5.4.8 Provide details of 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).

5.4.9 Will the GMO be removed completely from the trial site upon completion of the trial? If yes, provide details of how it will be destroyed/removed and disposed of. If no, complete section 11 of Part IV of the application.

5.5 What are the arrangements for producing the GMO in the quantities required for the trial release?

5.6 What are the arrangements for transporting the GMO to the trial release site(s)?

5.7 Will the GMO or its products enter the human or animal food chains as part of the field or clinical trial experiments?

5.7.1 If yes, complete section 12 of PART IV of the application.

5.7.2 If no, what measures will be taken to prevent human or animal ingestion of the GMO?

5.8 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.

6. MONITORING AND RISK MANAGEMENT PLAN

6.1 Provide a detailed supervision/monitoring and risk management plan 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, for ensuring the implementation and maintenance of containment measures, and for the monitoring of potential hazardous or deleterious effects that may result from the trial release of the GMO.

6.2 Describe any contingency plans and emergency procedures, especially with respect to containment of the GMO, 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.

TIER 2 (Supplementary Information)

PART IV (only sections that the applicant was referred to from Tier 1 need to be completed)

7. PHENOTYPIC CHARACTERISTICS THAT INCREASE THE RISK OF THE TRIAL RELEASE

(To be completed if you answered yes to changes in any one of the characteristics in section 2.4)

7.1 Does the genetic modification(s) result in changes in the host or unmodified organism in terms of the following?

(If yes for any one of the characteristics below, provide detailed information of the changes and the potential impact of the changes in the context of human and animal health and environmental risk or harm.)

7.1.1 Increased weediness

7.1.2 Increased risk of gene flow

7.1.3 Increased pest potential

7.1.4 Increased pathogenicity or host range

7.1.5 Increased persistence in the environment

7.1.6 Adverse impacts on non-target organisms

8. UNINTENDED EFFECTS

(To be completed if unintended effects were reported in section 4.6)

8.1 Provide detailed information on the assessment of unintended effects and the impact of the unintended effects on the traits and characteristics of the GMO, especially in the context of section 4.5.

8.2 Explain if or how the unintended effects may compromise the methods and measures to be used to:

8.2.1 Contain the GMO within the trial site.

8.2.2 Prevent the transfer of the GMO's nucleic acid sequences, particularly sequences that define the organism as a GMO, to other organisms in the release site and surrounding environment.

9. GENE DRIVES

(To be completed if you answered yes to the question in section 4.7)

9.1 Provide a detailed description of the genetic modifications that are designed to spread through a population at higher-than-normal rates of inheritance.

9.2 Describe the impacts that the genetic modifications have on:

9.2.1 The GMO.

9.2.2 Populations of the same species as the GMO.

9.2.3 Species other than the GMO and the whole ecosystem.

10. BRIEF SUMMARY OF TRIAL RELEASES UNDERTAKEN

(To be completed if you answered yes to the question in section 5.1)

Note that approval of a trial release application is not subject to provision of information on previous field or clinical trials. However, applicants are encouraged to provide the information if it is available.

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

(a) South Africa

(b) Other countries.

Your answers to (a) and (b) should include information on the country, year, location and the authority from which permission was obtained to run the field trials.

10.2 Trial release results:

10.2.1 For GM plants, provide a scientific summary of the field performance of the GM plants, including a scientific explanation of the efficacy of the introduced trait(s) for each of the previously authorised activities listed in 10.1.

10.2.2 For GMOs other than GM plants, such as GMO investigational medicinal products (including GMO vaccines), provide a scientific summary of the results for each of the previously authorised activities listed in 10.1.

11. PERSISTENCE AT THE TRIAL SITE

(To be completed if you answered no to the question in section 5.4.9)

11.1 If the GMO cannot or will not be removed completely from the trial site upon completion of the trial, address the following:

11.1.1 Will the GMO be able to propagate after completion of the trial?

11.1.2 Are there theoretical or foreseeable adverse impacts or consequences on human/animal health and the environment if the GMO persists at the trial site after the trial is completed?

11.1.3 When considering the points above, how will the trial site be managed or used after the trial is completed?

11.1.4 Can the GMO spread from trial site upon completion of the trial, and what impacts or consequences would such a spread have on human/animal health and the environment?

12. HUMAN AND ANIMAL HEALTH

(To be completed if you answered yes to the question in section 5.7)

12.1 Provide details of the reason that the GMO or its product(s) will enter the human and/or animal food chains.

12.2 Provide information on the toxicity to humans and animals of newly-expressed protein(s) (including any marker proteins) or new constituents other than proteins that are produced by the GMO.

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

12.4 Provide details of the quantities of the GMO or its products that will be consumed by humans and/or animals as part of the trial. Provide information on why the GMO does not represent a health risk to humans and/or animals that will consume the GMO as part of the trial.

Additional information for specific classes of GMOs

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

SECTION A: Trial release: GM plants

1. Provide information on how the GM plant differs from the unmodified 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 genetic modification(s) give rise to GM plants that are tolerant to agrochemicals, provide information on the registered agrochemicals that the GM plant will be tolerant to.

4. Provide information on registered agrochemicals that can be used to eliminate the GM plant from the environment.

5. Trial location(s):

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

5.2 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: Investigational medicinal products that contain or consist of GMOs

1. Provide details on the pathogenicity of the GMO in the investigational medicinal product (IMP), including evidence from the use of the host organism or other GMOs having the same host organism in present medicinal products either in use or under development, and the available treatment methods, if any.

2. For replication-deficient and conditionally replication-competent clinical vectors, discuss strategies to avoid contaminating replication-competent virus. Test methods for detection of replication-competent virus should be described.

3. Based on data obtained in contained experiments, what are the effects expected when the GMO IMP interacts with non-target species? Please supply experimental data. If data are unavailable, please provide a summary substantiated with references describing possible effects.

4. In the case of human clinical trials, provide details on any pre-clinical and clinical studies (if any) undertaken with the GMO IMP.

5. Provide details on safety and tolerability studies undertaken on the GMO IMP, including toxicology and biodistribution.

6. Provide details on allergenicity/reactogenicity/hypersensitivity studies undertaken on the GMO IMP.

7. What is the existing evidence regarding levels and duration of recombinant protein expression by the GMO in the target species?

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

9. Provide details on the risk and likelihood of integration of the GMO, or any of its components, into the trial participants' DNA. Provide evidence, if any, on the duration of expression.

10. In the case of human clinical trials, what are the risks and likelihood of infection of healthcare professionals and/or close contacts of the human clinical trial participants (including vulnerable groups, such as immunocompromised individuals). How pathogenic would the GMO be in such individuals?

11. In the case of non-human trials, what are the risks and likelihood of infection of animal handlers, workers and/or their close contacts (including vulnerable groups, such as immunocompromised individuals). How pathogenic would the GMO be in such individuals?

12. Indicate if there is no possible release of the GMO into the environment either because there is no shedding or spreading of the GMO into the environment by animals or human trial participants, or because proper management procedures

and/or working practices are in place to prevent release? Provide evidence from preclinical and/or clinical testing to substantiate your answer.

13. Indicate if there is a probability of release into the environment when the trial participant leaves the clinic and can still shed and spread the GMO, or an animal handler is exposed following shedding during an animal trial, thereby potentially exposing his/her close contacts and the environment to the GMO, or there are not sufficient management procedures or working practices in place to avoid exposure of close contacts and the environment.

If yes:

13.1 Evaluate at which stage of the trial the general population and the environment can be exposed to the GMO due to shedding.

13.2 Specify the estimated duration of shedding.

13.3 Provide data on GMO shedding from any previous trials. If there are no prior clinical data with the same GMO, the potential for shedding should be discussed based on non-clinical data and/or clinical experience from related GMOs. The relevance of the data to the product in the current application should be explained considering, in particular, the dose and route of administration.

13.4 Provide an estimation of GMO exposure and risk (tick the appropriate box below).

High	
Moderate	
Low	
Negligible	

Justify your answer. In addition, please provide quantitative data on how much shedding occurs.

13.5 Specify whether shedding will be investigated during this trial. Describe the methods used for detection of viral/vector shedding. Information on the specificity (including ability to detect revertants) and sensitivity thereof should be provided. Describe plans for protecting human and animal health and the environment in the event of an undesirable effect. Describe the instructions given to clinical trial participants to prevent dissemination of the GMO.

14. For non-human, animal vaccines, 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, and containment protocols.

15. What arrangements are proposed to dispose of waste containing any GMO IMP either during the trial release or once the trial release is completed? If applicable, also include decontamination and disposal of potentially contaminated waste that accumulates outside the trial site.

16. For human clinical trials, include the investigator's brochure and clinical trial protocols as annexures to the application.

Cartagena Protocol on Biosafety

PART VI (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 ……..

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 acknowledged 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 conduct a public notification in accordance with Regulation 9 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.