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TITLE: APPLICATION FOR CONFINED FIELD TRIAL OF A GENETICALLY MODIFIED ORGANISM UNDER THE NATIONAL BIOTECHNOLOGY AUTHORITY [*CHAP. 14:31*] OF 2006.

This form authorises a confined field trial release of a GMO.

SECTION A: ADMINISTRATIVE INFORMATION

1. Applicant: (a) Name:		
(b) Address:		
(c) Telephone Number:		
(d) Email Address:		
2. Details of Contact Person: (a) Name:		
(b) Designation:		
(c) Address:		
(d) Telephone Number:		
(e) Email address:		
3. List of Institutional Biosafety Committee Members		
4. Type of application	New application	
	Renewal	
5. Reference Number of a prior approved Contained Use of this GMO (if any):		

SECTION B: TYPE OF GENETICALLY MODIFIED ORGANISM

1. GMO Type:

Plant	
Animal	
Microorganism	
Vaccine	
Other	

**tick applicable*

Depending on the GMO Type ticked above, also complete: Section G (Vaccine-Specific Considerations) if Vaccine; Section H (Microorganism-Specific Considerations) if Microorganism; Section I (Animal-Specific Considerations) if Animal. Plant-specific biological risk and gene-flow questions are included within Section F below.

SECTION C: DESCRIPTION OF THE GMO AND GENETIC MODIFICATION

If this GMO was previously approved for Contained Use under the reference number given in Section A, and the description below is unchanged, you may write "As per NBA (GMO) 1-CU application [reference number]" in place of repeating the full description. Otherwise, complete this Part in full.

1. Description of the GMO:

Taxonomic Details	**GMO Trade Name**	**Unique identifier of the genetically modified organism**	**Introduced / Modified Trait(s) and Gene(s)**

2. Standard Trait Category (tick all that apply):

Herbicide Tolerance ☐
Modified Oil Composition ☐
Pharmaceutical ☐
Male Sterility/Restoration ☐
Virus Resistance ☐
Genetic Research ☐
Insect Resistance ☐
Stress Tolerance ☐

	Generation of Mutants ☐ Nutritional Change ☐ Fungal Resistance ☐ Other (specify) ☐
3. Information on the Vector, including its origin and whether it is disarmed:	
4. Name of Plasmid / Construct:	
5. Genetic Map of the Construct (attach a map for each construct; describe genes, regulatory elements, gene products and non-translated sequences):	

6. Description of Elements of the Construct(s) (complete for all constructs and GMO gene elements):

Genetic Element	Size (bp)	Source	Function

7. Mode of Action of the Trait (gene product, metabolic pathway(s) affected):	
8. For viral vectors: what genes were deleted from the parent virus, what accessory genes are supplied in trans, and what self-inactivation sequences (if any) are used?	
9. Where the introduced genetic material is intended to knock out the expression/function of an endogenous gene, describe the endogenous gene and its function:	

10. Method for detection of the genetically modified organism (analytical/laboratory method used to confirm GMO identity):	
11. Is the GMO registered in the country of origin?:	**YES** ☐ **NO** ☐ **NB -** If yes, attach Registration Certificate
12. Intellectual Property Ownership of the novel trait	
13. Description of the Genetic Modification (technique used, steps, transformation event)	
14. Does the GMO have a potentially unstable genotype?	
15. Survival rate of the GMO under conditions likely to be found in the trial area and surrounding environment	
16. Capability of the GMO to disperse from the trial area, and dispersal mechanisms:	
17. Frequency of reversion or loss of the genetic change:	

SECTION D: RECEIVING ENVIRONMENT – HABITAT AND ECOLOGY OF THE PARENT ORGANISM

1. Natural habitat and range of the parent organism	
2. Is the parent organism already present at or near the planned trial site? Provide available population data:	

3. Describe the known predators or parasites of the organism in Zimbabwe	
4. Could introduction of the GMO affect any beneficial function of the parent organism in the environment?	
5. If the recipient/parental (unmodified) organism is a pathogen, describe its: environmental stability; virulence/pathogenicity; host range; transmissibility; and treatment options:	
6. If the donor organism (the source of the genetic material) can cause disease in humans, animals, plants or fungi, describe how the donor genetic material contributes to the donor's: environmental stability; virulence/pathogenicity; host range; transmissibility; and treatment options:	

SECTION E: TRIAL SITE DESCRIPTION

1. Trial Site name(s)	
2. Location of proposed trial site(s) include map	
3. Trial site size, soil, groundwater, topography, flora and fauna, climate	
4. Former use of the site, and distance from surface waters	

and environmentally protected areas	
5. Description of the environment immediately surrounding the trial site	
6. Distance of the trial site from population centres and centres of agricultural activity	
7. Reasons for the choice of location:	

SECTION F: ISOLATION, CONFINEMENT AND SITE RESTORATION

Complete this sub-section where the GMO Type ticked in Section B is Plant. Not applicable to non-plant GMO types.

1. Is the parent plant, or a species/genus closely related to it, known to be a weed? If yes, describe the weediness of the plant/relatives:	
2. Does the plant produce any known toxins or allergenic products? If yes, describe, including the known or potential effects of the genetic modification on these products:	
3. Are sexually compatible wild or related plant species present in the area immediately surrounding the trial site, and what is their efficiency of hybridisation with the parent species?	
4. What are the pollen dispersal mechanisms of the parent species (biotic or abiotic	

vectors, maximum dispersal distance, pollen viability)?	
5. Are any characteristics of the GMO expected to be altered compared to the parent plant that affect the efficiency of gene transfer and introgression into sexually compatible species (e.g. flowering time, pollen production/viability)?	
6. What controls are proposed to restrict gene flow via pollen dispersal, and to restrict the spread of seeds or asexual propagules from the site, while the GM plants are growing?	

7. Isolation and Physical Confinement

(a) Genetic confinement measures (e.g. sterility, reproductive isolation, use of non-reproductive tissue)	
(b) Physical/spatial isolation measures and barriers planned to segregate the trial from the surrounding environment	
(c) Material confinement measures (handling, storage, disposal of plant/animal material generated by the trial)	
8. Arrangements for producing the GMO in quantity, and for transporting it to the trial site	

9. Quantity of the GMO to be released	
10. Provisions to remove or eliminate the GMO from the trial site (and any other affected place) on completion of the trial, and to restore the site to its original state:	
11. What measures are proposed to ensure ongoing access and control of the trial site for the duration of the trial and any post-trial monitoring period (e.g. lease/land-use agreements, landowner consent)?	

SECTION G: VACCINE-SPECIFIC CONSIDERATIONS

Complete this Part only where the GMO Type ticked in Section B is Vaccine.

1. For field trials involving vaccine organisms, what arrangements are proposed to dispose of waste containing any vaccine organisms?	
2. Will trial subjects/animals carry live vaccine organisms at the end of the trial? If so, will they be likely to disseminate the live vaccine organisms to the general population?	
3. Based on data obtained in contained experiments, what are the effects expected when the vaccine organism interacts with target and non-target species in the trial area	

and surrounding environment?	
4. What is the existing evidence regarding the level and duration of immunity produced in the target species?	
5. What challenge or other tests using virulent field strains are to be carried out on vaccinated animals?	
6. What is the likelihood that the host vaccine organism would be used in other human or animal vaccines?	
7. Would the use of this vaccine preclude the future use of the host vaccine organism for immunisation purposes?	

SECTION H: MICROORGANISM-SPECIFIC CONSIDERATIONS

Complete this Part only where the GMO Type ticked in Section B is Microorganism. Answer the sub-section(s) below relevant to the intended use of the micro-organism; more than one sub-section may apply.

1. Micro-organisms Associated with Plants

(a) What is the target plant?	
(b) Is the organism able to establish itself on or in non-target species in the surrounding environment?	
(c) To what extent does the organism survive and reproduce on or in the target plant, the rhizosphere of the target plant species, or other plant species in the trial site	

and surrounding environment?	
(d) What characteristic is intended to be imparted to the target plant species?	
(e) Can these characteristics be imparted to non-target plant species, especially those in the surrounding environment? If so, is the distribution and abundance of any non-target plant species likely to be affected?	
(f) In the case of soil organisms, what are the effects on organisms known to be beneficial to plants (e.g. *Rhizobium*, *Frankia*, mycorrhizal fungi) likely to be at the trial site?	
(g) In the case of soil organisms, what are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, nutrient levels)?	

2. Micro-organisms Associated with Animals

(a) What is the target animal species?	
(b) What is known about the organism's ability to survive and reproduce?	
(c) Is the organism able to establish itself in non-target species?	

(d) What characteristics are intended to be imparted to the target animal species?	
(e) Can these characteristics be imparted to non-target animal species? If so, are the distribution and abundance of non-target species likely to be affected?	
(f) In the case of domesticated animal species, can these characteristics be imparted to feral populations of the target species? If so, are the distribution and abundance of such feral populations likely to be affected?	

3. Micro-organisms Intended to Modify the Environment

(a) In the case of biological control organisms, what is the biological control target species?	
(b) What direct effects do the unmodified and modified organisms have on the target species, non-target species (including humans), and any plant or animal species being protected from the target species?	
(c) What is known about the organism's ability to survive and reproduce in association with the target species or substance?	

(d) Can the organism establish itself in association with non-target species or substances?	
(e) Does the organism produce metabolites which may have deleterious effects on other organisms, directly or through concentration in the food chain?	
(f) Can the modified genetic traits be transmitted to other micro-organisms likely to be in the environment? If so, are these likely to affect non-target species or substances?	
(g) 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)?	

4. Micro-organisms for Use in Food

(a) What relationship does the micro-organism or the introduced DNA have to known human pathogens?	
(b) What is the possibility that the micro-organism will produce metabolites which may have deleterious effects?	

SECTION I: ANIMAL-SPECIFIC CONSIDERATIONS

Complete this Part only where the GMO Type ticked in Section B is Animal. Answer the sub-section(s) below relevant to the intended use of the animal.

1. Terrestrial/Livestock Animals – Handling and Excretion Containment

(a) How will the animals be restrained during administration of the GMO? Will any sharp instruments be used?	
(b) If there is potential for aerosol generation, how will aerosols be contained?	
(c) Will the GMO be secreted or excreted from the animal? If yes, describe the proposed method for containment of the animals and the GMO at the trial site (including any aerosols):	

2. Fish and Other Aquatic Animals – Containment

(a) What measures ensure the physical integrity of ponds, tanks, or other structures confining the GMO at the trial site (e.g. secondary containment, screens, mesh sizing to prevent escape at all life stages)?	
(b) What are the arrangements for treatment of water discharged or drained from the trial site (e.g. effluent treatment, filtration, disinfection) before release to the environment?	
(c) What is the distance and hydrological connection (if	

any) between the trial site and the nearest natural waterway, and what flood-risk mitigation measures are in place?	
(d) Could the GMO survive, establish, or reproduce if it escaped into a natural waterway? What is the evidence for this?	
(e) Are wild or farmed populations of the same or a sexually/reproductively compatible species present in waterways near the trial site?	

3. Genetic and Breeding Considerations (applies to all animal GMO types)

(a) Will the animals in this planned field trial be allowed to breed? If not, is breeding planned for later stages, and are the arrangements for handling any offspring specified?	
(b) What are the desirable effects expected to result from the use of the modified animal (e.g. improved reproduction, weight gain, disease resistance)?	
(c) What undesirable effects may result from the trial (e.g. difficult birth, reduced fertility)?	
(d) Are any of the likely gains directly linked to losses in other characteristics of the species (e.g. increased growth rate accompanied by	

decreased wool or milk production)?	
(e) Can the genetic trait be transmitted by means other than normal reproduction?	
(f) Do feral populations of the species exist in Zimbabwe? If so, do the feral populations cause agricultural, environmental or disease-control problems?	
(g) Has any experimental work been done on the phenotypic expression of the novel genetic material in feral genomes (e.g. crossbreeding with captive feral animals)? If so, what were the results?	
(h) What is the likelihood of the novel genetic material entering the feral gene pool (e.g. by interbreeding with modified farm animals)?	
(i) Would entry of the novel genetic material into the feral gene pool affect the distribution and abundance of the feral population and its ability to cause agricultural, environmental or disease-control problems?	
(j) If no feral populations exist in Zimbabwe, would the imparted characteristics enhance the ability of the species to establish feral populations?	

SECTION J: TRIAL PROTOCOL

1. Aim of the proposed trial and intended eventual use of the GMO:	
2. Brief description of the activities to be conducted:	
3. List of parameters (agronomic, phenotypic, and compositional, as applicable) to be monitored, how it will be monitored and timing/frequency of monitoring for each	
4. If the trial is successful, is a General Release proposed? If so, indicate expected timing:	
5. Total planned period of the trial and proposed commencement date:	
6. Supervision and monitoring arrangements for the trial:	
7. Summary of contingency arrangements for extreme conditions (storms, floods, bushfires) during the trial (Attach detailed Contingency Plan):	

SECTION K: RISK ASSESSMENT

1. What potential hazards or deleterious effects resulting from the trial can be postulated? How and which of these will be monitored and evaluated? If some	

effects will not be monitored, why not?	
2. Have similar trials of similar GMOs been conducted before, in or outside Zimbabwe? What were the beneficial and adverse consequences?	
3. What evidence exists concerning the transferability of the inserted genetic trait to other organisms in the trial site and surrounding environment?	
4. Is the GMO intended to modify the characteristics or abundance of other species? If so, what are the target species and intended consequences?	
5. Are there unlikely but possible impacts of the trial? Would these have substantial impacts if they occurred, and does the protocol monitor these low-probability risks?	
6. What are the consequences of the organism remaining in the environment beyond the planned trial period?	
7. Compared to the parent/unmodified organism, is the GMO expected to be more harmful to people? Provide evidence or a rationale.	
8. Compared to the parent/unmodified organism, is the GMO expected to be	

more harmful to organisms other than people (animals, plants, micro-organisms)? Provide evidence or a rationale.	
9. Compared to the parent/unmodified organism, is the GMO's phenotype altered such that it could cause greater environmental harm (e.g. changes to fire regime, nutrient levels, soil stability)? Provide evidence or a rationale.	

SECTION L: APPLICATION COMPONENTS

1. I have attached the following to this application form (Highlight using a tick)

☐ Genetic Map(s) of the Construct(s)

☐ Risk Assessment Report(s)

☐ Detailed Trial Protocol

☐ Contingency Plan

☐ Confidential Commercial Information (CCI) Declaration (if applicable)

☐ List of IBC members

☐ IBC endorsement of this application

DECLARATION

I understand that, under section 10 of the Regulations, I must notify the Authority within 48 hours of new information with significant risk consequences, and that wilful non-disclosure is an offence. I certify that the information provided in this application, and in all attachments, is true and complete to the best of my knowledge.

Name of Applicant: _____

Position within the applying organisation: _____

Date of Submission: _____

Signature: _____

Official Stamp of applying Organisation should be placed here

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) ENDORSEMENT

This application has been reviewed by the Institutional Biosafety Committee named in Part 1, which endorses its submission to the National Biotechnology Authority.

Name of IBC Chairperson: _____

Signature: _____

Date: _____

FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY

....

Name of Officer Designation

.....

Signature Date &Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a)Approval without conditions recommended:

.....

(b) Approval recommended subject to the following conditions:

.....

(c) Rejection recommended for the following reasons:

.....

NOTIFICATION PARTICULARS

The decision on this application was notified to the applicant:

ON ..... SIGNED .....