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

To: The Chief Executive Officer & Registrar

National Biotechnology Authority

This form authorises unconfined, commercial-scale release of a GMO into the environment.

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. Type of application	New application	
	Renewal	
4. Reference Number of a prior approved CFT of this GMO (if any):		
5. Status of applications or approvals for this specific GMO/trait (as opposed to similar GMOs generally) in Zimbabwe or other jurisdictions:		

SECTION B: TYPE OF GENETICALLY MODIFIED ORGANISM

1. GMO Type:

Plant	
Animal	
Microorganism	
Vaccine	
Other (Specify)	

**tick applicable*

Depending on the GMO Type ticked above, also complete: Section F (Additional Consideration for Genetically Modified Plants) if Plant; Section G (Vaccine-Specific Considerations) if Vaccine; Section H (Microorganism-Specific Considerations) if Microorganism; Section I (Animal-Specific Considerations) if Animal.

SECTION C: DESCRIPTION OF THE GMO AND GENETIC MODIFICATION

1. Description of the GMO:

Taxonomic Details (genus/species)	**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. Description of the Genetic Modification (technique used, steps, transformation event)	
13. Provide evidence indicating the number of complete or partial copies of the introduced genetic material present in the GMO(s) proposed for release:	
14. Provide evidence that the introduced genetic modification is stably inherited in successive generations:	
15. Provide evidence that the genetic modification is functioning as intended in the GMO(s) (e.g. confirmed expression of the introduced trait):	
16. Where more than one GMO line/event is proposed for release, provide the testing methodology used to confirm identity for each line/event:	

SECTION D: SUMMARY OF CONFINED FIELD TRIAL RESULTS

This part must be completed for all applications unless the National Biotechnology Authority has, in writing, exempted the requirement for a prior Confined Field Trial

1. Summary of the Confined Field Trial(s) conducted (dates, sites, protocols)	
2. Beneficial and adverse consequences observed during the trial(s)	
3. Monitoring data on survival, dispersal, and gene flow from the trial(s)	
4. Have similar general releases of similar GMOs been made before, in or outside Zimbabwe? What were the outcomes?	

SECTION E: RECEIVING ENVIRONMENT

1. National distribution of the parent organism, and its centres of diversity:	
2. Wild or sexually-compatible relatives present in Zimbabwe, and their distribution:	
3. Agro-ecological zones in which release is intended:	
4. Gene-flow pathways relevant to this organism (e.g. pollen spread, seed dispersal, horizontal gene transfer):	
5. Could the release affect any beneficial function of the	

parent organism in the environment?	

SECTION F: PLANT SPECIFIC CONSIDERATIONS

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

1. Are any members of the genus of modified plants known to be weeds?	
2. Should the imparted characteristic escape into a wild population, would it affect the distribution and abundance of that population, and cause agricultural, environmental or disease-control problems?	
3. Has the modified plant been shown to be non-toxic to animals and humans? Could any toxic products concentrate in the natural or human food chain?	

SECTION G: VACCINE-SPECIFIC CONSIDERATIONS

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

1. For general release of vaccine organisms, what arrangements are proposed to dispose of waste containing any vaccine organisms?	
2. Will recipients/animals carry live vaccine organisms following release? If so, are they likely to disseminate the live vaccine organisms to the general population?	

3. Based on data obtained in confined field trials, what are the effects expected when the vaccine organism interacts with target and non-target species at national scale?	
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 have been 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 general release 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 receiving 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 nationally?	
(d) What characteristic is intended to be imparted to the target plant species?	
(e) Can these characteristics be imparted to non-target plant species? 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)?	
(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 nationally?	
(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 at national scale?	

(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 general release of the modified organism (e.g. increased resistance)?	

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, where applicable? Will any sharp instruments be used?	
(b) If there is potential for aerosol generation, how will aerosols be managed at national scale?	
(c) Will the GMO be secreted or excreted from the animal? If yes, describe the expected environmental fate of the GMO (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 following general release (e.g. secondary containment, screens, mesh sizing to prevent escape at all life stages), where release is not fully unconfined to open waterways?	
(b) What are the arrangements for treatment of water discharged from any managed facilities associated with the release (e.g. effluent treatment, filtration,	

disinfection) before release to the environment?	
(c) What is the expected distribution of the GMO relative to natural waterways nationally, and what is the likelihood of establishment in unintended water bodies?	
(d) Could the GMO survive, establish, or reproduce in natural waterways beyond the intended release area? What is the evidence for this?	
(e) Are wild or farmed populations of the same or a sexually/reproductively compatible species present nationally, and what is the potential for interbreeding or competitive displacement?	

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

(a) Will the animals be allowed to breed following general release? Are arrangements for handling 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 general release (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: PRODUCT DESCRIPTION AND RELEASE

1. Description of the intended product (e.g. seed, grain, animal product, vaccine, other):	
2. Intended scale of release (area/quantity) and geographic scope within Zimbabwe:	
3. Intended market (domestic / export; food, feed, processing, or other use):	
4. Desirable effects expected to result from the use of the modified organism:	
5. Are any of the likely gains directly linked to losses in other characteristics of the species	

SECTION K: RISK ASSESSMENT

1. FOOD AND FEED SAFETY

Complete only where the GMO or its product is intended for use, or likely to be used, in food or feed)

(a) Is the GMO or its product intended for use, or likely to be used, in food or feed?	
(b) If yes, provide a food/feed safety assessment consistent with the Codex Alimentarius Principles for the Risk	

Analysis of Foods Derived from Modern Biotechnology and the Codex Guideline for Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (or the equivalent Codex guideline for the relevant organism type):	
(c) Compositional analysis relative to the conventional counterpart (key nutrients, anti-nutrients, toxicants, allergens)	
(d) Allergenicity assessment	
(e) Proposed labelling and traceability arrangements, if the GMO or its product enters the food/feed chain	

2. ENVIRONMENTAL RISK ASSESSMENT

(a) What potential hazards or deleterious effects arising from the general release can be postulated at national/population scale? How and which of these will be monitored and evaluated? If some effects will not be monitored, why not?	
(b) Have similar general releases of similar GMOs been made before, in or outside Zimbabwe? What were the beneficial and adverse consequences?	
(c) What evidence exists concerning the transferability of the inserted genetic trait to	

other organisms in the receiving environment?	
(d) Is the GMO intended to modify the characteristics or abundance of other species? If so, what are the target species and intended consequences?	
(e) Compared to the parent/unmodified organism, is the GMO expected to be more harmful to people? Provide evidence or a rationale.	
(f) 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.	
(g) 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.	
(h) If the introduced genetic material were transferred to a different sexually compatible species, would the resultant organism be more harmful to people, other organisms, or the environment than the non-GM sexually compatible	

species? Provide evidence or a rationale.	
(i) Are there unlikely but possible impacts of the release? Would these have substantial impacts if they occurred, and does the monitoring plan address these low-probability risks?	

SECTION L: RISK MANAGEMENT AND POST-REGISTRATION MONITORING

1. Risk management measures at population/commercial scale to protect biological diversity and human health during general release (attach full Risk Management Plan):	
2. Post-Registration (Post-Release) Monitoring Plan – summary (Attach full plan)	
3. Other regulatory agencies consulted before the intended release	

SECTION M: APPLICATION COMPONENTS

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

☐ Genetic Map(s) of the Construct(s)

☐ Risk Assessment Report(s)

☐ Summary of Confined Field Trial results

☐ Product Certificate from Country of Origin

☐ Monitoring Plan

☐ Risk Management Plan

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

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

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 .....