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

This form authorises laboratory, greenhouse, growth-chamber or other physically contained work with a GMO where the organism and its products are not released 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		

SECTION B: TYPE OF GENETICALLY MODIFIED ORGANISM

1. GMO Type:	Plant		
	Animal		
	Microorganism		
	Vaccine		

	Other (Specify):	
	**tick applicable*	

SECTION C: DESCRIPTION OF THE GMO AND GENETIC MODIFICATION

1. Description of the GMO:

Taxonomic Details	**GMO Trade Name**	**Unique identifier of the genetically modified organism**	**Introduced / modified trait and genes**

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. Is the GMO registered in the country of origin?	**YES** ☐ **NO** ☐ **NB:** If yes please attach Registration Certificate
11. Intellectual Property Ownership of the novel trait	
12. Description of the Genetic Modification (technique used, steps, transformation event)	
13. Does the GMO have a potentially unstable genotype?	
14. Method(s) used to test for batch-to-batch consistency	
15. Method for detection of the genetically modified organism (analytical/laboratory method	

used to confirm GMO identity)	
16. Potential adverse effects on biological diversity and human health under contained conditions:	
17. Uncertainties and assumptions in the risk assessment:	

SECTION D: DONOR AND RECIPIENT/PARENTAL ORGANISM

1. Information on the donor organism (identity, origin)	
2. Information on the recipient/parental (unmodified) organism, including origin:	
3. Describe the unmodified/parent organism's natural habitat and range known	
4. Does the unmodified form(s) have any adverse effect on humans, animals, plants, agricultural production, or the environment? Provide details:	
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: FACILITY AND CONTAINMENT DETAILS

1. Facility Name and Location	
2. Facility Registration Number	
3. List of the Institutional Biosafety Committee members	
4. Number of other contained-use activities currently approved within the same facility	
5. Biosafety Level assigned to the facility (per Certificate of Facility Registration)	
6. Type of Facility (tick as appropriate)	Microbiological laboratory ☐ Pilot plant ☐ Production facility ☐ Greenhouse ☐ Animal breeding facility ☐ Other (specify) ☐
7. Layout of the premises and location of main facilities (attach plan)	
8. Containment attributes of the facility:	

SECTION F: GREENHOUSE / PLANT-SPECIFIC CONTAINMENT CONTROLS

Complete this Part only where the GMO Type ticked in Section B is Plant and/or the facility type ticked in Section E includes a Greenhouse. This Part does not apply to laboratory-only or non-plant contained use.

1. Biological Risk: Weediness, Toxicity and Wild Relatives

(a) 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:	
(b) 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:	
(c) Are sexually compatible wild or related plant species present in the area immediately surrounding the facility?	

2. Proposed Herbicide/Pesticide Use (if any):

Name of Pesticide/Herbicide	Active Ingredient	Total Area to be Sprayed (m^2/hectare)

3. Work Schedule (post-approval) of Key Activities:

Dates of Movement of Material	Planting (anticipated)	Harvest/Sampling (anticipated)

4. Plan for recording quantities of seed planted/GMO used, and for accounting for any excess:	

5. Will plants be allowed to set seed or to reproduce?	Yes ☐ No ☐
6. Will any harvested plant material be retained from the trial?	Yes ☐ No ☐
7. If retained: type, quantity to be retained, and purpose of retaining the material:	
8. Storage of harvested material: storage method, storage location, person responsible (name and telephone), and proposed storage records:	

SECTION G: VACCINE-SPECIFIC CONSIDERATIONS

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

1. For contained use activities involving vaccine organisms, what arrangements are proposed to dispose of waste containing any vaccine organisms?	
2. Will the subjects/animals carry live vaccine organisms at the end of the contained use activity? 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 contained-use premises 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 contained-use premises 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 in the contained-use premises?	
(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 (including any aerosols):	

2. Fish and Other Aquatic Animals – Containment

(a) What measures ensure the physical integrity of tanks, ponds or other containment structures used to hold the GMO (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 facility (e.g. effluent treatment, filtration, disinfection) before release to the environment?	
(c) What is the distance and hydrological connection (if any) between the facility 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 facility?	

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

(a) Will the animals in this planned contained use 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 contained use (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: DESCRIPTION OF CONTAINED-USE ACTIVITIES AND PROTOCOL

1. Brief description of the proposed contained-use activity	

2. Purpose of the contained use (e.g. research, laboratory control, manufacture)	
3. If the contained-use work is successful, is a Confined Field Trial or General Release planned? If so, provide expected timeline	
4. Total period of contained use and proposed date of commencement	
5. Protocol – experimental design	
6. Protocol – nature and type of data to be collected	
7. Amount of GMO to be used (volume of culture, number of plants or animals)	
8. Arrangements for producing the GMO in quantity	

SECTION K: RISK MANAGEMENT, WASTE MANAGEMENT AND TRANSPORT

1. Description of potential risks associated with the contained-use activities to be undertaken	
2. Supervision and monitoring arrangements for the contained-use activities	
3. Validated procedures for routine monitoring detection of the GMO within and around the facility (ongoing operational monitoring, not GMO identification)	

4. Validated methods for inactivation of the GMO and decontamination of an affected space (including any animals used in conjunction with the GMO, where relevant)	
5. Summary of emergency response in the event of an accident	
6. Waste management plan for material disposed of during and after the contained-use activities (including animal carcasses/waste, where relevant)	
7. Consequences of the GMO being accidentally released into the environment from the contained-use premises	
8. Plan for training of employees prior to commencement of contained-use activities, and plan for refresher training:	
9. Arrangements for transporting the GMO to the contained-use premises	
10. Means of Packaging and Labelling:	

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)

☐ Reports of Analysis of Product from Accredited/Approved Laboratories

☐ Contingency Plan

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

☐ List of IBC members

☐ IBC endorsement of this application

☐ Declaration of Intellectual Property or Patents or 'Commercial-In-Confidence' Information

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

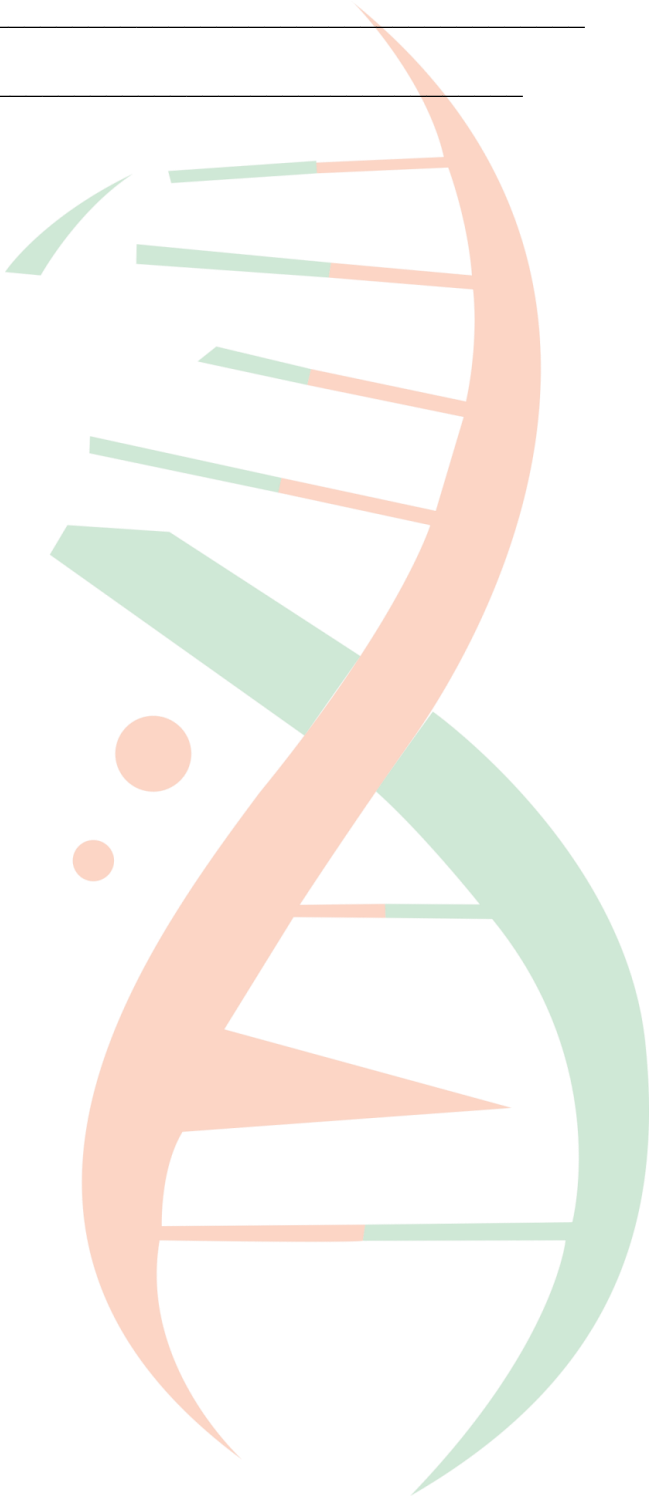
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) ENDORSEMENT

This application has been reviewed by the Institutional Biosafety Committee named in Section E, 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 .....