NATIONAL BIOSAFETY AUTHORITY

GUIDELINES AND CHECKLISTS FOR THE RISK ASSESSMENT AND CERTIFICATION OF FACILITIES DEALING WITH GENETICALLY MODIFIED ORGANISMS

JUNE 2013

FOREWORD

The Government of Kenya as stated in the Vision 2030 recognizes biotechnology as one of the key sectors that have potential to alleviate poverty and improve the well being of its people. The National Biosafety Authority was established in 2010 to regulate all activities involving genetically modified organisms. All activities with genetically modified organisms in Kenya are regulated under the Biosafety Act, 2009 (Act No. 2, of 2009). The Objectives of the Act are to facilitate research into, and minimize the risks that may be posed by genetically modified organisms; provide guidelines that ensure an adequate level of protection for the safe transfer, handling and use of GMOs; and establish a transparent, science-based and predictable process for reviewing and making decisions on the transfer, handling and use of GMOs and related activities. Kenya is a signatory of the Cartagena Protocol on Biosafety which seeks to protect biological diversity from the potential risks posed by living modified organisms that are derived from modern biotechnology.

The National Biosafety Authority (NBA) is mandated to ensure safety to human and animal health and provide protection of the environment from harmful effects that may result from genetically modified organisms. The Authority has made great strides in establishing strong Biosafety framework in Kenya by developing and publishing the implementing Biosafety Regulations namely; Contained use, Environmental Release, Import, Export and Transit, and, Labelling Regulations. These regulations lay down clear procedures on handling GMOs whether plants, animals or microorganisms.

The Authority has also developed and implemented various operational, mandatory and departmental procedures based on the International Organization for Standardization (ISO) standards. These also include operation manuals that supplement the Authority's regulatory requirements. This manual provides instructions for Biosafety inspectors carrying out risk assessment for experimental facilities handling genetically modified organisms. The guidelines will also be used for certification of such facilities after inspection. It is important that the Biosafety inspectors be well trained and equipped to carry out inspections and identify non-compliance whenever identified. However, it is the responsibility of the facility manager to ensure compliance with the guidelines and all other appropriate regulations.

These guidelines were prepared through a series of consultative meetings. We are grateful for the active participation and cooperation demonstrated by the regulatory agencies and other stakeholders during the process of developing this document. We sincerely thank the Program for Biosafety Systems (PBS) – Kenya Chapter for their financial and technical support in development of these guidelines which will go a long way in improving the biosafety framework in Kenya.

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ABBREVIATIONS AND ACRONYMS

BCH	Biosafety Clearing House
BSC	Biosafety Cabinet
BSL	Biosafety Level
CBD	Convention on Biological Diversity
DNA	Deoxyribonucleic Acid
FAO	Food and Agriculture Organization of the United Nations
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
ISO	International Organization for Standardization
NBA	National Biosafety Authority
NIH	National Institute of Health
PPE	Personal Protective Equipment
rDNA	Recombinant Deoxyribonucleic Acid
RG	Risk Group
WHO	World Health Organization

DEFINITION OF TERMS

The following are some definitions of terms used within this document;
Authority: means the National Biosafety Authority

Biosafety inspector: a person appointed by the Cabinet Secretary under the recommendation of the Authority, and by notice in the gazette. The inspectors functions are to monitor compliance with the Biosafety Act [1] and other regulations, undertake inspections and submit reports to the Authority, and to perform any other duties assigned by the Authority.

Biosafety level : refers to the degree of protection that is provided to personnel, community and the environment by a testing facility

Biosafety level: is the level of the containment precautions required to isolate biological agents in an enclosed facility based on the risks they pose to animal and human health and the environment. The levels of containment range from the lowest Biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4).

Containment : refers to isolation of lab research procedures/materials in environmentally and biologically secure rooms or cabinets, to prevent accidental infection of workers or release into the surrounding community during research

Conventional counterpart: a related organism/variety, its components and/or products for which there is experience of establishing safety based on its common use [3].

Facility manual : refers to a handbook that sets biological safety policies for a facility in relation to;

- Preventing environmental contamination;
- Protecting experimental materials
- Protecting workers from exposure to infectious agents; and
- Complying with the national and international regulations.

Genetically modified organism: means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques [9];

Green house facility: includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas and is considered part of the confinement area [12].

Green house: refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof

are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth [12].

Hazard: a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect [4].

Insert: means an additional length of base pairs in deoxyribonucleic acid (DNA) that has been introduced into that DNA

Institutional Biosafety Committee: a committee established under regulations 6 of the Biosafety Act [1]

Microorganism: a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, an animal or plant cell in culture, an artificially created cell into which it is intended genetic material will be introduced and a prion [6].

'Modern Biotechnology' includes the application of-

a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or
b) fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive and recombinant barriers and which are not techniques used in traditional breeding and selection.

Organism: any biological entity capable of replication or of transferring genetic material and includes a microorganism but does not include a human, human embryo or human admixed embryo[6].

Personal protective equipment: refers to specialized clothing or equipment worn by laboratory users for protection against health and safety hazards

Personal protective equipment: equipment worn to minimize exposure to a variety of hazards. Examples include such items as gloves, foot and eye protection, respirators and full body suits.

Risk Analysis: a process consisting of three components: risk assessment, risk management and risk communication [4].
Risk Assessment: a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization [4].

Risk Characterization: the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse

health effects in a given population based on hazard identification, hazard characterization and exposure assessment [4].

Risk Communication: the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions [4].

Risk Management: the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk: a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food [4]

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CHAPTER ONE
INTRODUCTION

1.1 Background of NBA

The National Biosafety Authority (NBA) is a state corporation in Kenya mandated to ensure safety of human and animal health and provide adequate protection of the environment from harmful effects that may result from genetically modified organisms (GMOs).

The Authority was established pursuant to the provisions of the Biosafety Act, 2009 to regulate all activities involving GMOs in food, feed, research, industry, trade and environmental release and it fulfills its mandate by ensuring and assuring safe development, transfer, handling and use of GMOs in Kenya.

NBA has made great strides in establishing strong Biosafety framework in Kenya by developing and publishing the implementing Biosafety Regulations. These regulations laid down a clear procedure on handling GMOs whether plants, animals or microorganisms. NBA is the National Focal Point for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) and is mandated to implement the provisions of the Cartagena Protocol on all Biosafety matters pertaining to GMOs.

1.2 Vision Statement

A World-class Biosafety Agency

1.3 Mission Statement

To ensure and assure safe development, transfer, handling and use of genetically modified organisms (GMOs) in Kenya.

1.4 Our Core Values

a) Integrity
b) Professionalism
c) Transparency
d) Accountability

1.5 Our Objectives

a) To facilitate responsible research and minimize risks that may be posed by genetically modified organisms;

b) To ensure adequate level of protection in the development, transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and

c) To establish a transparent, science-based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities.

1.6 Our Core Functions

The Biosafety Act no.2 of 2009 lists the functions of NBA as follows:

a) Consider and determine applications for approval for the development, transfer, handling and use of genetically modified organisms, and related activities in accordance with the provisions of the Biosafety Act;

b) Co-ordinate, monitor and assess activities relating to the safe development, transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health and the environment;

c) Co-ordinate research and surveys in matters relating to the safe development, transfer, handling and use of genetically modified organisms, and to collect, collate and disseminate information about the findings of such research, investigation or survey;

d) Identify national requirements for manpower development and capacity building in biosafety;

e) Advise the Government on legislative and other measures relating to the safe development, transfer, handling and use of genetically modified organisms;

f) Promote awareness and education among the general public in matters relating to biosafety; and

g) Establish and maintain a Biosafety clearing house (BCH) to serve as a means through which information is made available to facilitate exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms;

h) To exercise and perform all other functions and powers conferred on by the Act.

CHAPTER TWO

2.0 Introduction

Prior to conducting any work with genetically modified organisms, an application of such an activity must be made to the National Biosafety Authority as stipulated in the Biosafety Act, 2009. The applicant must submit the information stipulated in the third schedule of the Contained use Regulations, 2011. NBA afterwards conducts risk assessment to identify and evaluate the potential adverse effects of the genetically modified organisms on human health and the environment as stipulated in the fifth schedule of the Biosafety Act, 2009. Such an assessment is also intended to prevent laboratory acquired infections while dealing with biological agents, prevent escape of the GM organisms into the environment, classify biological agents according to risk and appropriate containment laboratories to ensure safety.

The classification into containment levels will be determined by the handling requirements of the work processes, or the degree of hazard to humans and environment. The containment requirements will provide the end user and the Biosafety inspector with a description of the minimum containment required for handling the genetically modified organism safely. The containment descriptions will include:

i) The facility design
ii) Regular and operational practices such as engineering, technical, administrative physical requirements
iii) Personnel competency and training
iv) Occupational health and safety

2.1 Scope

The scope of the risk assessment of experimental facilities manual will be limited to laboratory, greenhouses and animal houses handling genetically modified organisms. It will focus on containment requirements with emphasis on facility design elements, operational practices (engineering, technical, administrative and physical requirements), personnel competence, and occupational health requirements.

NB: Risk assessment of the genetically modified organisms that will be handled in every facility will be evaluated during the application process for contained use.

2.2 Objectives of the manual

The main purpose of this manual is to provide a guideline to Biosafety Inspectors and researchers on how to undertake risk assessment of experimental facilities handling genetically modified organisms and provide a checklist for use during certification inspections. The manual shall also serve as a guide to institutions undertaking work on genetically modified organism's in order to help them identify the areas of assessment and ensure that they comply.

2.3 Risk assessment of genetically modified organisms

Prior to approval of an activity involving genetically modified organisms, a comprehensive analysis should be carried out to ascertain its safety to human health and the environment. Such an analysis is called risk assessment. It should be carried out on a case by case and step by step basis [7]. Risk assessment should also determine the containment level of the facility to be used for activities involving the GMO. This is achieved by determining the nature of the DNA sequences to be transferred, donor organism of the insert, pathogenicity of the GMO, and the effects associated with the GMO [8] .

The scientific data to be used for risk assessment should be of adequate quantity, based on sound research methodologies, carried out using appropriate techniques and analyzed using appropriate analytical techniques. The data and information should be peer reviewed or able to stand a scientific peer review[3]. Data and information will be obtained from the developer of the product, peer-reviewed scientific literature, regulatory agencies, international bodies, independent scientists, and other appropriate sources [3]. Scientific data from other sources generated using other different methodologies and in different environs should also be considered.
The applicant should provide the information requested in the third schedule of the Contained use Regulations [9].

2.3.1 Factors to be considered when determining the effects of a GMO to human and animal health

The following factors shall be considered during a risk assessment for work with GMOs [8]:

(a) The characteristics of the inserted gene
Where the expression product of the insert gene is known, an assessment of its product in relation to human health is required. Such products may include:

i) Toxins
ii) Cytokines
iii) Hormones
iv) Gene expression regulators
v) Virulence factors or enhancers
vi) Oncogenic gene sequences
vii) Antibiotic resistance
viii) allergens

(b) The characteristics of the host organism
This comprises of hazards that may be associated with the host organism such as:

i) Susceptibility of the host
ii) Pathogenicity or infectivity of the host microorganism
iii) Modification of the host range
iv) The immune status of the host

v) and the effects of exposure on the host organism

(c) Hazards arising from the alteration of existing pathogenic traits
Alteration of genes whose products are known not to be harmful may result into production of harmful traits. In order to identify such hazards, the following should be considered:

i) Does the alteration result into increased infectivity and pathogenicity?
ii) Could the insertion of the foreign gene overcome any disabling mutation in the host?
iii) Does the inserted gene lead to the expression of pathogenic determinants from other organisms?
iv) If the insert gene does express pathogenic determinants, does this influence the pathogenicity of the GMO?
v) Are there available treatments?
vi) Will the gene alteration result to an influence of the organisms antimicrobial susceptibility?
vii) Can the GMO be eradicated?
viii) Is the expressed product associated to allergenicity in humans?

Also to be considered is whether there is any literature and information on the host organism; the routes of exposure to humans such as skin contact, inhalation, ingestion e.t.c.; availability of vaccines; previous history of infections; presence of effective containment measures; and possible infection to other species.

The following shall be considered as harmful effects to human health:

i) disease to humans also taking into account toxicity and allergenicity
ii) disease to plants or animals
iii) any deleterious effects as a result of failure to treat a disease or provide effective prophylaxis
iv) any deleterious effects as a result of release of the microorganism into the environment
v) any deleterious effects as a result of transfer of genetic material to other naturally occurring organisms

2.3.2 Steps of risk assessment

A risk assessment shall involve the following steps;

(a) an identification of any genotype and phenotypic characteristics associated with the genetically modified organisms that may have adverse effects on the environment and on human health
(b) an evaluation of the likelihood of these adverse effects being realized, taking into account the level and the kind of exposure of the likely potential receiving environment of the genetically modified organisms
(c) an evaluation of the consequences should this effects be realized

(d) an estimation of the overall risk posed by the genetically modified organisms based on the evaluation of the likelihood and consequences of the identified adverse effects being realized
(e) a recommendation as to whether or not the risks are acceptable or manageable, including identification of strategies to manage these risks
(f) consideration of any relevant legislation both locally and internationally
(g) Following steps (a) to (f), identify the level of risk associated with the GMO or its product
(h) Identification of the appropriate containment measures taking into consideration the level of the risk associated with the GMO.
(i) classification of the contained use according to NBA's containment guidelines
(j) where there is uncertainty regarding the level of risk, the Authority may request for further information on the specific issues of concern or may recommend implementing appropriate risk management strategies and monitoring the genetically modified organisms in the receiving environment.
(k) review of the classification based on the assessment

2.3.3 Requirements for safety assessments

The Codex Alimentarius Commissions is an international body established by FAO and the WHO that aims to ensure the safety of human health and fair trade of food by developing harmonized International food standards, guidelines and code of practice [10]. The body has over 180 members with Kenya being one of them. We do encourage applicants to also refer to the Commissions standards at http://www.codexalimentarius.org/ specifically the principles and guidelines for food safety assessment of foods derived from modern biotechnology [3] and make sure that they comply.

Conventional foods have been used for decades and are widely considered as safe. Safety of foods derived from modern biotechnology should therefore be determined after comparison with their conventional counterparts with an aim of seeking to find any similarities or differences. Risk assessment identifies whether a hazard, nutritional difference, or any other effect is present in food derived from a GMO compared to its conventional counterpart. If a difference is present, it should be characterized to determine its effect to human health and the environment [3].

According to Codex Alimentarius Commission [4], a safety assessment of food derived from a GMO is characterized by the assessment of the whole or part of the food compared to an equal portion of the conventional counterpart. This process entails:

i) identification of new or altered hazards:
Hazard identification is the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods [4]. It is the first step of risk assessment and seeks to identify any similarities and/or differences between the rDNA plant or its derived products and

their equivalent conventional counterparts. It takes into account the compositional analysis and agronomic and phenotypic characteristics [11].

ii) hazard characterization:
It is the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food [4].
It aims to evaluate the differences present (toxicological and nutritional effects) in the rDNA plant or its derived products and assess its implications on human health. Experiments using animal models may provide useful information for hazard characterization [11].

iii) exposure assessment:
It is the qualitative and/or quantitative evaluation of the exposure to products and derivatives of recombinant-DNA plants compared to their conventional counterparts. It takes into account the magnitude, frequency and duration of the exposure [11]. For example it may seek to determine if there will be an increased preference to GM food and feed compared to their conventional counterparts and if so, then more focus should be placed on such GM products.
A post-market surveillance may be necessary to confirm the findings of the exposure assessment [11].

iv) risk characterization
It is the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, characterization and exposure assessment [4].

Based on the above assessments, it may be possible to determine if the risk characterization is sufficient or not. If the exposure to the GM product is expected to be significantly high, then more data on toxicity may be required [11].

2.4 Risk assessment for facilities handling genetically modified organisms

The contained use regulations [9] should be adhered to. These regulations guide all activities involving GMOs under containment and are applied during research on GMOs while still in the laboratory, greenhouse, and animal house. In order to ascertain that all work processes on the GMOs are properly maintained and that the safety of the personnel and surrounding environment is assured, proper containment measures must be adhered to. The choice of the containment facility for work with a particular GMO will be based on its risk assessment as determined by NBA.

Genetically modified microorganisms (biological agents) shall be classified according to the risks they pose to human and animal health, and the environment. They shall be classified into four risk groups based on the following criteria:

i) ability to cause harm or damage

ii) magnitude/severity of the harm or damage caused
iii) probability of the harm spreading to the population
iv) risk of damage to the environment, or economic loss
v) availability of treatment and/or vaccinations

Criteria for classification into Risk Group 1

- Agents posing low individual and community risk
- Agents unlikely to cause disease in humans and animals
- Agents unlikely to cause any effects on the environment

Criteria for classification into Risk Group 2

- Agents posing moderate individual and community risk
- Agents that can cause disease to human or animals but are unlikely to spread to the community
- Exposures to these agents rarely cause serious disease to human and animal and effective prophylaxis and treatment is available
- Agents are unlikely to cause serious environmental effects

Criteria for classification into Risk Group 3

- Agents posing a high individual risk but low community risk
- Agents causing severe human and animal disease but the risks of spreading into the community are minimal
- Availability of effective treatment and preventive measures
- Agents that can cause serious environmental damage in case of accidental release

Criteria for classification into Risk Group 4

- Agents posing a high individual risk and high community risk
- Agents causing severe human or animal disease and are likely to be spread into the community
- Lack of effective treatment and preventive measure
- Agents are likely to cause severe environmental damage in case of accidental release

The risk group corresponds to the Biosafety level of the facility (BSL) e.g. work on Risk group 1 agents should be carried out in a BSL-1 containment or confinement facility (laboratory, green-house, animal house) while that of risk group 4 on BSL-4 respectively. However, the required work procedures including the nature of modification may influence the level of containment. A risk group one organism might be required to be handled in a BSL-2 or higher containment facility based on the requirements of the work processes and the nature of modification to be performed.

Apart from the facility design elements, the operational practices will also be considered while carrying out risk assessment of experimental facilities. This will include:

a) personnel training

b) work practices/standard operating procedures
c) equipment
d) administrative control
e) occupational health and safety
f) personal protective equipment
g) decontamination and disposal of wastes
h) Biosafety facility manuals
i) other potential exposures

The facility design and structure is important to ensure that the organisms are adequately contained hence preventing escape or release into the surrounding environment. Personnel training is also key in ensuring that they are competent in the work practices. The integrity of safety equipments and all other equipments used in the work processes should also be evaluated.

In addition, the facility should have adequate access control that will prevent entry of unauthorized persons and also monitor those who enter the premises. The health status of the laboratory personnel should also be evaluated. This will screen for any laboratory acquired infections and also ensure that the staff is in good health as they perform their duties.

Personal protective equipment should be adequate for the work processes. The type, condition and size of the PPE should be appropriate. In conclusion, all generated wastes including spills should be adequately decontaminated and/or disinfected. All processes and equipments used for disinfection or decontamination should be evaluated for quality control.

The above requirements are elaborated in Annexes 1, 2 and 3 of these guidelines. They provide checklists to be used by Biosafety inspectors while carrying out risk assessment of the experimental facility. This checklists will also be used during inspections prior to certification of the GMO handling facility.

CHAPTER 3

RISK MANAGEMENT AND RISK COMMUNICATION

3.1 Risk management

The purpose of risk management is to protect the health and safety of people and the environment by controlling or mitigating risk. It should encompass preparation of a risk management plan which includes training on general risk management measures, evaluation and mitigation of risks, and proposed license conditions. It should also include monitoring and reviewing which details measures to assess effectiveness of all steps in risk analysis including post release review of commercial release of GMOs.

Risk evaluation is carried out during risk management to determine, based on risk assessment outcomes, which risks need mitigation. Risk is evaluated against the objective of protecting the health and safety of people and the environment. Risk evaluation may also aid in consideration of whether the proposed dealings should proceed, need further assessment or, require collection of additional information during the release.

When risk requires mitigation, options to reduce, eliminate or avoid the risk are identified and assessed, and selected management measures are implemented. Options to reduce exposure to the GMO or its products and limit opportunities for the spread and persistence of the GMO, its progeny or the introduced genes to the environment must be considered. Selection of risk management measures is made according to their efficacy and efficiency, commensurate with the level of risk. If risk treatment measures are selected for an identified risk, then risk should be reduced sufficiently such that any residual risk does not compromise protection of the health and safety of the people and the environment.

Applicants are required to have contingency plans in case of an emergency. The nature of such plans may vary depending on the license and nature of dealings. All approvals include a requirement that NBA be informed if there is an unintentional release of the GMO. Monitoring and reviewing all steps in risk analysis is to ensure the right procedures are undertaken, each step is done correctly and that the outcomes remain valid in the light of future findings or changes in circumstances. A number of both internal and external feedback mechanisms can be used to maintain the effectiveness and efficacy of risk assessment and risk management, and which consider the concerns of all interested and affected stakeholders.

Monitoring and reviewing contributes to identifying situations where treatment measures are not adequately managing the risks, either as a result of non-compliance or because of changed circumstances or unintended or unexpected effects. It also facilitates ongoing review of the conclusion of risk assessment and of the risk treatment options.

3.2 Risk communication

Generally the perception of risk by individuals is dependent on a large number of factors including knowledge of the risk, its impact on that individual, the potential for long-term consequences and widespread effects, the extent to which the individual can influence the risk and possible benefits (if any) that might accrue to individuals, groups or society as a whole.

The aim of risk communication is to promote a clear understanding of all aspects of risk and the particular positions of interested parties. Specifically it aims to provide information about risk to help people make decisions, to minimize conflicts, to improve understanding of perceptions and positions and to achieve equitable outcomes.

Public perceptions of the risks associated with gene technology range across a wide spectrum of positions and include ethical concerns and social issues, such as multinational companies might seek to achieve market dominance by controlling access to the technology.

To be effective, risk communication requires an exchange of knowledge rather than a one-way transfer of information. It is most effective when it is two-way and with an opportunity for discussion and feedback.

CHAPTER FOUR

ANNEXES

ANNEX 1 – CHECKLIST FOR RISK ASSESSMENT AND CERTIFICATION OF CONTAINMENT FACILITIES FOR BIOSAFETY LEVEL 1

The following information should be provided by the principal investigator who is responsible for management of work at the GMO experimental facility (laboratory, green-house, animal house):

CONTAINMENT REQUIREMENTS OF A BIOSAFETY LEVEL 1 EXPERIMENTAL FACILITY				
1	Name of Principal Investigator including those responsible for supervision and safety			<*insert text*>
2	Training and qualifications of persons responsible for supervision and training			<*insert text*>
3	Details of Institutional Biosafety Committee			<*insert text*>
4	Details of the facility including the address and contact information			<*insert text*>
5	Description of the nature of work involving contained use or confinement of a GMO including that already undertaken			<*insert text*>
A. ANIMAL UNIT				
	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
7	Is the animal unit separated from other buildings? This is optional for this level.			
8	Are the animal facilities separated by lockable doors? This is optional for this level.			
9	Does the design of the animal facilities facilitate decontamination (waterproof and easily washable material, cages etc.)? This is optional for this level.			
10	Is the floor constructed with easily washable material?			

11	Are the floor to wall, wall to ceiling and wall to wall junctions rounded for easy cleaning?			
12	Are all joints between door frames and wall sealed?			
15	Are used cages decontaminated and transported in a manner that does not contaminate the environment?			
16	Wastes have to be sterilized and incinerated			
17	Are hands decontaminated and washed after handling animals and waste?			
18	Is access to animal facilities restricted?			
19	Does the animal unit have installed devices to detect fires, ventilation and heating failures and the intrusion of unauthorized personnel?			
20	Has an inspection window been fitted in the door where appropriate?			
21	Are the animal facilities adequately aerated?			
22	Is the facility constructed in such a way not to allow entry of wild forms of the animals into the facility?			
23	Are there measures in place that control undesired species such as insects and rodents into the facility?			
24	Are male and female species separated to avoid reproductive transmission (unless reproductive studies are part of the experiment)?			
25	Are accidents, bites and scratches caused by animals reported to the facility manager who in turn has to make a written report?			
26	Are personnel trained in the handling of the animals?			
27	Are written records about the transfer of foreign genes, the breeding experiments and the disposal of animals maintained?			
28	Are transgenic animals easily identified? The insert can deal as an additional marker			
29	Is eating and smoking prohibited in the facility?			

30	Are protective clothing and shoes worn and changed or cleaned when leaving the facility?			
32	Are rodent barriers installed in front of doors and are alternative doors self-closing to rooms where animals are housed and handled to prevent the escape of animals?			
33	Are animal species housed in appropriate cages, runs, pens suitable for their requirements?			
34	Are animals admitted other than for experimental purposes?			
39	Is an autoclave available when genetically modified micro-organisms are used in experiments?			
40	Are contaminated material and waste from experiments where genetically modified micro-organisms are used inactivated?			
47	Does the facility have windows that open?			

B. GREENHOUSES

	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
59	Is contaminated run-off water controlled? This is optional for this level.			
60	Is there a suitable program to prevent plant pests, weeds, insects and rodents?			
61	Are there measures in place to control undesired species such as weeds, insects, rodents, and arthropods?			
62	Are the protective structures in place sufficient to minimise dissemination of genetically modified micro-organisms during transfer of living material between the greenhouses?			
65	Is the greenhouse floor made of gravel or other greenhouse-typical material? At			

	least the pavement should be solid, e.g. of concrete.			
69	Does the facility design minimize escape of GMOs?			
75	Are protective clothing worn outside the greenhouse?			
79	Are injuries reported immediately to the project leader?			
80	Are there written instructions for greenhouse practices and procedures?			
83	Is an air intake screening and motorized or gravity-driven exhaust fan louver in place?			
86	Are genetically modified plants made unviable e.g. by cutting off blossoms prior to disposal?			

C. LABORATORY ACTIVITIES

	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
	1. Physical control measures **(a) Facility design**			
90	Is the facility dealing with viable micro-organisms separated from the environment (having a closed system)?			
94	Does the facility have windows that open? This is optional for this level.			
	(b) Containment facility			
112	Are the facility surfaces easy to clean and resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents?			
114	Is the suitability of any chemical disinfectants to be used checked? This is optional for this level.			
115	Is the autoclave installed on site?			
117	Is there a hand-wash sink, detergent, disinfectant and paper towels in place? (a)			

118	Does the containment facility ensure that there is no leakage or escape of genetically modified organisms? This is optional for this level.			
119	Is the design of waste transport containers appropriate to prevent contamination of the surroundings?			
120	Is the design of containers for the transport of genetically modified organisms inside the facility adequate to prevent escape of the organisms?			
121	Are the laboratory equipments appropriate for the work to be performed and do they prevent the escape of the genetically modified organisms?			
125	Is there an observation window or alternative in place so that occupants can be seen? This is optional for this level.			
	2. Safety Management **(a) Work procedures**			
126	Are procedures or activities that may generate aerosols containing GMOs conducted in a certified BSC or other aerosol containment equipment?			
127	Are procedures done in a manner that prevents or minimises aerosol formation?			
128	Are engineering control measures exercised and supplemented with appropriate personal protective clothing and equipment where necessary?			
129	Are equipments adequately tested and maintained (calibration/ certification/ servicing)?			
130	Are doors closed while working?			
133	Are workers given adequate information on safety matters and suitably trained? Note: Training should include the following points: (a) the existence and application of written work procedures (b) the procecures for using particular pieces of equipment (c) spillage control and other emergency procedures			
134	Are the process steps at which hazardous			

	quantities of aerosols formed determined? This is optional for this level.			
135	Are genetically modified organisms transported within the facility in closed, robust and leakproofed containers? This is optional for this level.			
136	Are work surfaces decontaminated daily and after a spillage?			
137	Are effective disinfectants and specified disinfection procedures in case of spillage of genetically modified organisms in place?			
138	Are genetically modified organisms in contaminated material and waste should inactivated?			
141	Are benches free from clutter?			
142	Is the identity of genetically modified organisms regularly checked to avoid the culturing of incorrect stains? Note: The time between these checks is dependent on the potential hazard. This is optional for this level.			
143	In case of an incorrect identity of a genetically modified organism, are there corrective actions in place following the results of the controls and is there a way to register them?			
144	Do laboratory users ensure that the performance of safety equipment is validated? Note: This should include: (a) Certification/calibration of equipment (b) maintenance of the equipment (c) markers used to verify the efficiency of autoclaves			
145	Is mouth pipetting prohibited?			
146	Is eating, drinking, smoking, applying cosmetics prohibited in the work area?			
147	Is skin contact with recombinant DNA material avoided?			
148	Are hands washed after handling recombinant DNA and before leaving the laboratory?			
149	Are protective clothing always worn while			

	working in the laboratory? Note: The following PPE must be worn by all authorised persons in the work area(s): (a) protective clothing to protect the front part of the body (e.g. long-sleeved, back fastening, tight-wristed protective clothing); (b) closed footwear; (c) gloves; (d) eye protection; and (e) waterproof dressings on all broken skin.			
150	Are the protective clothing decontaminated before laundering?			
151	Are the protective clothing and street wear kept separate?			
152	Has an insect and rodent control programme been implemented?			
153	Has the workplace and environmental exposure to any physical, chemical or biological agent been kept to the lowest practicable level?			
154	Have tests, when necessary, for the presence of viable genetically modified organisms outside the primary physical containment been performed?			
155	Has the use of sharps been avoided where possible?			
156	Are contaminated syringes / sharps disposed of in a 'Sharps bin' and incinerated?			
158	Are Institutional Biosafety Committees or sub-committees in place and constituted as per the NBA Contained Use Regulations, 2011?			
159	Are non experimental animals restricted from entry into the laboratory?			
161	Is sample collection, movement of addition of materials into a containment facility and transfer of viable micro-organisms to another containment facility performed as appropriate?			
162	Is safe storage of biological agents adhered to?			
163	Are non-essential personal effects,			

	including handbags, mobile phones, portable music devices, and other non-essential electronic equipment prohibited in the facility			
164	Is the transport of the GMOs in accordance with the Biosafety (*Handling, Packaging, Storage and Transporting of GMOs Regulations) 2013?*			
	(b) Institutional matters and documentation relating to the safe handling of genetically modified organisms			
165	Is there a copy (electronic or paper) of the Biosafety facility manual available? Note: The Biosafety facility manual must document the following: (a) the contact details of the facility manager (b) a list of persons authorized to use the facility (c) the persons to contact in case of an emergency (d) the layout and operation (including design limits) of the facility (e) details of all organisms being handled in the facility, the risks associated with the use of these organisms, and the management strategies for these risks (f) the procedures that must be followed by all persons entering and exiting the facility, including the use of PPE including the donning and doffing off procedures (g) the procedures for the operation and use of the BSC (if applicable) and any other specialized aerosol containment equipment (h) the assessment of and the procedures for the use of sharps (if allowed) (i) the procedures for the use of normal and emergency communication systems (j) the procedures for the movement of all equipment into and out of the facility, including			

	decontamination (k) the procedures for decontamination of GMOs, including operation and use of the autoclave (l) the procedures for waste and effluent disposal, including transport procedures (m) the procedures for the transport of GMOs within the facility, including for storage of GMOs (n) the procedures for the transport of GMOs outside the facility (e.g. transport to another BSL-1 facility) as outlined in the Biosafety (*Handling, Packaging, Storage and Transporting of GMOs Regulations) 2013* (o) the procedures for carrying out risk assessment (p) the procedures for training of new staff (q) health assessment of laboratory workers			
166	Are equipment operation and troubleshooting manuals placed within the facility?			
168	Are written standard operating procedures provided where appropriate to ensure safety?			
169	Is there a documentation of the appointment of the Biosafety Officer (BSO)?			
170	Has a project leader been appointed?			
171	Is a description of the tasks of the Biosafety Officer (BSO) with respect to safety; internal control; accident/incident; response and preparedness; internal counseling, advice and education; and, reporting in place?			
172	Is a description of the tasks of the project leader available with respect to: (a) everyday management (b) drawing-up and executing work-protocol?			
173	Is there a clear description of separation of			

	responsibilities and tasks between the Biosafety Officer and the Project Leader?			
174				
176	Have the following documents been centrally held within an institution undertaking contained use?: (a) a paper copy of the Biosafety facility manual (b) records that cover any sites for storage of genetically modified organisms outside of containment facilities (c) records of internally organized inspections (d) records of accidents, including evaluation and any remedial action (e) a list of other data and documents that are held at other locations within the institution?			
177	Are the following documents available? Note: They could be held separately from the main records (see section 176 above): (a) records of staff involved in contained use facilities indicating their experience and training in Biosafety and the type of projects in which they have been employed (b) results of procedures for checking the purity and identity of the genetically modified organisms (c) results of the testing of laboratory equipment (e.g. autoclaves) (d) a list of stored genetically modified organisms for each storage facility (e) work protocols for particular experimental procedures?			
	Contingency plans			
179	Are emergency response plans, including the procedures and use of specialized equipment required for responding to the following in place?: (i) spills of GMOs in the facility (both inside and outside BSCs) and spills while			

	transporting GMOs outside the facility (ii) accidental exposure to GMOs used within the facility, including procedures for the management and treatment of persons suspected to be infected or contaminated with or exposed escape of animals containing GMOs within the facility (iii) alarms for fire or loss of pressure (iv) loss, theft or unintentional release of GMOs from the facility (v) failure of power or ventilation systems (vi) fire and natural disasters (vii) medical emergencies or serious injury to persons within the facility (viii) security threats other life-threatening situations?			

ANNEX 2 - CHECKLIST FOR RISK ASSESSMENT AND CERTIFICATION OF CONTAINMENT FACILITIES FOR BIOSAFETY LEVEL 2

The following information should be provided by the principal investigator who is responsible for management of work at the GMO experimental facility (laboratory, green-house, animal house, or confined field trial):

CONTAINMENT REQUIREMENTS OF A BIOSAFETY LEVEL 2 EXPERIMENTAL FACILITY				
1	Name of Principal Investigator including those responsible for supervision and safety			<*insert text*>
2	Training and qualifications of persons responsible for supervision and training			<*insert text*>
3	Details of Institutional Biosafety Committee			<*insert text*>
4	Details of the facility including the address and contact information			<*insert text*>
5	Description of the nature of work involving contained use or confinement of a genetically modified organism including that already undertaken			<*insert text*>
A. ANIMAL UNIT				
	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
7	Is the animal unit separated from other buildings? This is optional for this level.			
8	Are the animal facilities separated by lockable doors? This is optional for this level.			
9	Does the design of the animal facilities facilitate decontamination (waterproof and easily washable material, cages etc.)? This is optional for this level.			
10	Is the floor constructed with easily washable material?			
11	Are the floors to wall, wall to ceiling and wall to wall junctions rounded for easy cleaning?			
12	Are all joints between door frames and			

	wall sealed?			
13	Are animal facilities cleaned regularly and are sinks disinfected regularly?			
14	Are all surfaces disinfected after work?			
15	Are used cages decontaminated and transported in a manner that does not contaminate the environment?			
16	Wastes have to be sterilized and incinerated			
17	Are hands decontaminated and washed after handling animals and waste?			
18	Is access to animal facilities restricted?			
19	Does the animal unit have installed devices to detect fires, ventilation and heating failures and the intrusion of unauthorized personnel?			
20	Has an inspection window been fitted in the door where appropriate?			
21	Are the animal facilities adequately aerated?			
22	Is the facility constructed in such a way not to allow entry of wild forms of the animals into the facility?			
23	Are there measures in place that control undesired species such as insects and rodents into the facility?			
24	Are male and female species separated to avoid reproductive transmission (unless reproductive studies are part of the experiment)?			
25	Are accidents, bites and scratches caused by animals reported to the facility manager who in turn has to make a written report?			
26	Are personnel trained in the handling of the animals?			
27	Are written records about the transfer of foreign genes, the breeding experiments and the disposal of animals maintained?			
28	Are transgenic animals easily identified? The insert can deal as an additional marker			
29	Is eating and smoking prohibited in the facility?			
30	Are protective clothing and shoes worn			

	and changed or cleaned when leaving the facility?			
31	Are rodent barriers installed in front of doors and are alternative doors self-closing to rooms where animals are housed and handled to prevent the escape of animals?			
32	Are animal species housed in appropriate cages, runs, pens suitable for their requirements?			
33	Are animals admitted other than for experimental purposes?			
34	Is an autoclave available when genetically modified micro-organisms are used in experiments?			
35	Are contaminated material and waste from experiments where genetically modified micro-organisms are used inactivated?			
36	Are used cages decontaminated and transported in a manner that does not contaminate the environment?			
37	Wastes have to be sterilized and incinerated			
38	Are hands decontaminated and washed after handling animals and waste?			
39	Is access to animal facilities restricted?			
40	Does the animal unit have installed devices to detect fires, ventilation and heating failures and the intrusion of unauthorized personnel?			
41	If genetically modified organisms can be transmitted, are working tools and equipment sterilized?			
42	Is waste contaminated with genetically modified organisms transported in suitable containers?			
43	Are genetically modified organisms transported in break proofed and closed containers?			
44	Where risk assessment indicates the animal room and contents will need to be fumigated, is the room capable of being sealed by appropriate means? Note: consideration should be given to			

	the means of removing or extracting the fumigant.			
45	Is there a hygiene plan in place?			
47	Does the facility have windows that open?			
49	Where mechanical ventilation is provided, is the airflow inwards? Note: Air should not be recirculated to any part of the building.			

B. GREENHOUSES

	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
57	Is the Greenhouse a permanent structure? Note: The structural design of the greenhouse should be adequate to withstand extreme weather conditions.			
58	Are internal walls, ceilings and floors resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area? Note: All penetrations into these structures and surfaces should be sealed (e.g. cables, pipes) (optional)			
59	Is contaminated run-off water controlled? Note: This is optional for this level.			
60	Is there a suitable program to prevent plant pests, weeds, insects and rodents?			
61	Are there measures in place to control undesired species such as weeds, insects, rodents, and arthropods?			
62	Are the protective structures in place sufficient to minimise dissemination of genetically modified micro-organisms during transfer of living material between the greenhouses?			
63	Are GMOs transported in suitable closed non- breakable containers?			
65	Is the greenhouse floor made of gravel or other greenhouse-typical material? At			

	least the pavement should be solid, e.g. of concrete.			
66	Is the ground of the greenhouse made of water impermeable material? Note: Gravel and other porous material under the planting tables are suitable if there is only a minor possibility that reproducible biological material can be transmitted through the soil. In this case earth beds are also possible.			
67	If part of the ground consists of gravel, are appropriate treatments made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel?			
69	Does the facility design minimize escape of GMOs?			
72	Is a Biohazard sign at placed at the entry?			
73	Is there a sign posted indicating: (optional) (a) That a restricted experiment is in progress (b) Name of responsible individual (c) Plants (organisms) in use (d) Special requirements for using the area? Note: this requirement is optional for this containment level			
74	Is access limited to the project leader/facility manager and personnel authorized by him?			
75	Are protective clothing worn outside the greenhouse?			
76	Are separate facilities for storing protective and street clothing available?			
79	Are injuries reported immediately to the project leader?			
80	Are there written instructions for greenhouse practices and procedures?			
81	Does the facility have a hand disinfection apparatus and wash basin?			
83	Is an air intake screening and motorized or gravity-driven exhaust fan louver in place?			
87	Are equipments which were in contact			

	with GMOs sterilized before cleaning, if the contact may lead to the transmission of GMOs?			
88	Is an Autoclave available within the facility?			
	C. LABORATORY ACTIVITIES			
	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
	1. Physical control measures **(a) Facility design**			
90	Is the facility dealing with viable micro-organisms separated from the environment (having a closed system)?			
92	Is there restricted access to the facility (e.g. use of electronic cards, passwords)?			
94	Does the facility have windows that open? This is optional for this level.			
95	Is a Biohazard sign placed on the entrance door of the facility?			
96	Is there a sign at laboratory entrance indicating: (a) special hazard signs if an organism containing rDNA needs special provision for persons entering the laboratory (b) names of occupants who have access to the laboratory?			
	(b) Containment equipment			
111	Does the facility contain at least one certified Biological Safety Cabinet (BSC)? Note: The choice of the BSC must be appropriate for the work to be performed and should be placed at an appropriate position			
112	Are the facility surfaces easy to clean and resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents?			

113	Is the suitability of the equipments to be used checked prior to installation for safety purposes?			
114	Is the suitability of any chemical disinfectants to be used checked? This is optional for this level.			
115	Is the autoclave installed on site?			
117	Is there a hand-wash sink, detergent, disinfectant and paper towels in place? (a)			
118	Does the containment facility ensure that there is no leakage or escape of genetically modified organisms? This is optional for this level.			
119	Is the design of waste transport containers appropriate to prevent contamination of the surroundings?			
120	Is the design of containers for the transport of genetically modified organisms inside the facility adequate to prevent escape of the organisms?			
121	Are the laboratory equipments appropriate for the work to be performed and do they prevent the escape of the genetically modified organisms?			
122	Are contaminated filters sterilized onsite and sealed in a plastic bag for later sterilization?			
125	Is there an observation window or alternative in place so that occupants can be seen? This is optional for this level.			
	2. Safety Management **(a) Work procedures**			
126	Are procedures or activities that may generate aerosols containing GMOs conducted in a certified BSC or other aerosol containment equipment?			
127	Are procedures done in a manner that prevents or minimises aerosol formation?			
128	Are engineering control measures exercised and supplemented with appropriate personal protective clothing and equipment where necessary?			
129	Are equipments adequately tested and maintained (calibration/ certification/			

	servicing)?			
130	Are doors closed while working?			
132	Is access to the laboratory restricted when experiments are in progress?			
133	Are workers given adequate information on safety matters and suitably trained? Note: Training should include the following points: (d) the existence and application of written work procedures (e) the procedures for using particular pieces of equipment (a) spillage control and other emergency procedures			
134	Are the process steps at which hazardous quantities of aerosols formed determined? This is optional for this level.			
135	Are genetically modified organisms transported within the facility in closed, robust and leakproofed containers? This is optional for this level.			
136	Are work surfaces decontaminated daily and after a spillage?			
137	Are effective disinfectants and specified disinfection procedures in case of spillage of genetically modified organisms in place?			
138	Are genetically modified organisms in contaminated material and waste inactivated?			
141	Are benches free from clutter?			
142	Is the identity of the genetically modified organisms regularly checked to avoid the culturing of incorrect stains? Note: The time between these checks should dependent upon the potential hazard.			
143	In case of an incorrect identity of a genetically modified organism, are there corrective actions in place following the results of the controls and is there a way to register them?			
144	Do laboratory users ensure that the performance of safety equipment is validated?			

	Note: This should include: (d) Certification/calibration of equipment (e) maintenance of the equipment (a) markers used to verify the efficiency of autoclaves			
145	Is mouth pipetting prohibited?			
146	Is eating, drinking, smoking, applying cosmetics prohibited in the work area?			
147	Is skin contact with recombinant DNA material avoided?			
148	Are hands washed after handling recombinant DNA and before leaving the laboratory?			
149	Are protective clothing always worn while working in the laboratory? Note: The following PPE must be worn by all authorised persons in the work area(s): (f) protective clothing to protect the front part of the body (e.g. long-sleeved, back fastening, tight-wristed protective clothing); (g) closed footwear; (h) gloves; (i) eye protection; and (a) waterproof dressings on all broken skin.			
150	Are the protective clothing decontaminated before laundering?			
151	Are the protective clothing and street wear kept separate?			
152	Has an insect and rodent control programme been implemented?			
153	Has the workplace and environmental exposure to any physical, chemical or biological agent been kept to the lowest practicable level?			
154	Have tests, when necessary, for the presence of viable genetically modified organisms outside the primary physical containment been performed?			
155	Has the use of sharps been avoided where possible?			
156	Are contaminated syringes / sharps disposed of in a ‘Sharps bin’ and			

	incinerated?			
157	Where appropriate, are the personnel vaccinated against the agents to be handled?			
158	Are Institutional Biosafety Committees or sub-committees in place and constituted as per the NBA Contained Use Regulations, 2011?			
159	Are non experimental animals restricted from entry into the laboratory?			
160	Where appropriate, are serum samples taken from workers and stored to provide baseline information in the event of an unexplained illness? Note: this requirement is optional for this containment level			
161	Is sample collection, movement of addition of materials into a containment facility and transfer of viable micro-organisms to another containment facility performed as appropriate?			
162	Is safe storage of biological agents adhered to?			
163	Are non-essential personal effects, including handbags, mobile phones, portable music devices, and other non-essential electronic equipment prohibited in the facility			
164	Is the transport of the GMOs in accordance with the Biosafety (*Handling, Packaging, Storage and Transporting of GMOs Regulations) 2013?*			
	(b) Institutional matters and documentation relating to the safe handling of genetically modified organisms			
165	Is there a copy (electronic or paper) of the Biosafety facility manual available? Note: The Biosafety facility manual must document the following: (a) the contact details of the facility manager (b) a list of persons authorized to use the facility (c) the persons to contact in case of an emergency (d) the layout and operation (including design limits) of the facility			

	(e) details of all organisms being handled in the facility, the risks associated with the use of these organisms, and the management strategies for these risks (f) the procedures that must be followed by all persons entering and exiting the facility, including the use of PPE including the donning and doffing off procedures (g) the procedures for the operation and use of the BSC (if applicable) and any other specialized aerosol containment equipment (h) the assessment of and the procedures for the use of sharps (if allowed) (i) the procedures for the use of normal and emergency communication systems (j) the procedures for the movement of all equipment into and out of the facility, including decontamination (k) the procedures for decontamination of GMOs, including operation and use of the autoclave (l) the procedures for waste and effluent disposal, including transport procedures (m) the procedures for the transport of GMOs within the facility, including for storage of GMOs (n) the procedures for the transport of GMOs outside the facility (e.g. transport to another BSL-1 facility) as outlined in the Biosafety (*Handling, Packaging, Storage and Transporting of GMOs Regulations) 2013* (o) the procedures for carrying out risk assessment (p) the procedures for training of new staff			

	(q) health assessment of laboratory workers			
166	Are equipment operation and troubleshooting manuals placed within the facility?			
167	Is a hygiene plan in place			
168	Are written standard operating procedures provided where appropriate to ensure safety?			
169	Is there a documentation of the appointment of the Biosafety Officer (BSO)?			
170	Has a project leader been appointed?			
171	Is a description of the tasks of the Biosafety Officer (BSO) with respect to safety; internal control; accident/incident; response and preparedness; internal counseling, advice and education; and, reporting in place?			
172	Is a description of the tasks of the project leader available with respect to: (a) everyday management drawing-up and executing work-protocol?			
174				
176	Have the following documents been centrally held within an institution undertaking contained use?: (f) a paper copy of the Biosafety facility manual (g) records that cover any sites for storage of genetically modified organisms outside of containment facilities (h) records of internally organized inspections (i) records of accidents, including evaluation and any remedial action (a) a list of other data and documents that are held at other locations within the institution?			
177	Are the following documents available? Note: They could be held separately from the main records (see section 176 above): (a) records of staff involved in contained use facilities indicating			

	their experience and training in Biosafety and the type of projects in which they have been employed (b) results of procedures for checking the purity and identity of the genetically modified organisms (c) results of the testing of laboratory equipment (e.g. autoclaves) (d) a list of stored genetically modified organisms for each storage facility (a) work protocols for particular experimental procedures?			
	Contingency plans			
179	Are emergency response plans, including the procedures and use of specialized equipment required for responding to the following in place?: (i) spills of GMOs in the facility (both inside and outside BSCs) and spills while transporting GMOs outside the facility (ii) accidental exposure to GMOs used within the facility, including procedures for the management and treatment of persons suspected to be infected or contaminated with or exposed escape of animals containing GMOs within the facility (iii) alarms for fire or loss of pressure (iv) loss, theft or unintentional release of GMOs from the facility (v) failure of power or ventilation systems (vi) fire and natural disasters (vii) medical emergencies or serious injury to persons within the facility (viii) security threats other life-threatening situations?			

180	Are there written procedures present for: (a) internal notification of incidents (e.g. spillages) (b) external notification in case of serious risk (c) accident response (measures, reporting, evaluation) (d) emergency preparedness actions and counter-measures in case of accidents or incidents?			

ANNEX 3 - CHECKLIST FOR RISK ASSESSMENT AND CERTIFICATION OF CONTAINMENT FACILITIES FOR CONTAINMENT LEVEL 3

Genetically modified organisms classified as Risk group 3 agents shall be handled in Biosafety level 3 (BSL-3) facilities (animal unit, green house, or laboratory).

CONTAINMENT REQUIREMENTS OF A CONTAINMENT LEVEL 3 EXPERIMENTAL FACILITY				
1	Name of Principal Investigator including those responsible for supervision and safety			<*insert text*>
2	Training and qualifications of persons responsible for supervision and training			<*insert text*>
3	Details of Institutional Biosafety Committee			<*insert text*>
4	Details of the facility including the address and contact information			<*insert text*>
5	Description of the nature of work involving contained use or confinement of a genetically modified organism including that already undertaken			<*insert text*>
A. ANIMAL UNIT				
	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
7	Is the animal unit separated from other buildings? This is optional for this level.			
8	Are the animal facilities separated by lockable doors? This is optional for this level.			
9	Does the design of the animal facilities facilitate decontamination (waterproof and easily washable material, cages etc.)? This is optional for this level.			
10	Is the floor constructed with easily washable material?			
11	Are the floors to wall, wall to ceiling and wall to wall junctions rounded for easy cleaning?			
12	Are all joints between door frames and wall sealed?			

13	Animal facilities have to be cleaned regularly. Sinks have to be disinfected regularly.			
14	All surfaces have to be disinfected after work			
15	Are used cages decontaminated and transported in a manner that does not contaminate the environment?			
16	Wastes have to be sterilized and incinerated			
17	Are hands decontaminated and washed after handling animals and waste?			
18	Is access to animal facilities restricted?			
19	Does the animal unit have installed devices to detect fires, ventilation and heating failures and the intrusion of unauthorized personnel?			
20	Has an inspection window been fitted in the door where appropriate?			
21	Are the animal facilities adequately aerated?			
22	Is the facility constructed in such a way not to allow entry of wild forms of the animals into the facility?			
23	Are there measures in place that control undesired species such as insects and rodents into the facility?			
24	Are male and female species separated to avoid reproductive transmission (unless reproductive studies are part of the experiment)?			
25	Are accidents, bites and scratches caused by animals reported to the facility manager who in turn has to make a written report?			
26	Are personnel trained in the handling of the animals?			
27	Are written records about the transfer of foreign genes, the breeding experiments and the disposal of animals maintained?			
28	Are transgenic animals easily identified? The insert can deal as an additional marker			
29	Is eating and smoking prohibited in the facility?			

30	Are protective clothing and shoes worn and changed or cleaned when leaving the facility?			
31	Are rodent barriers installed in front of doors and are alternative doors self-closing to rooms where animals are housed and handled to prevent the escape of animals?			
32	Are animal species housed in appropriate cages, runs, pens suitable for their requirements?			
33	Are animals admitted other than for experimental purposes?			
34	Is an autoclave available when genetically modified micro-organisms are used in experiments?			
35	Are contaminated material and waste from experiments where genetically modified micro-organisms are used inactivated?			
36	Are used cages decontaminated and transported in a manner that does not contaminate the environment?			
37	Wastes have to be sterilized and incinerated			
38	Are hands decontaminated and washed after handling animals and waste?			
39	Is access to animal facilities restricted?			
40	Does the animal unit have installed devices to detect fires, ventilation and heating failures and the intrusion of unauthorized personnel?			
41	If genetically modified organisms can be transmitted, are working tools and equipment sterilized?			
42	Is waste contaminated with genetically modified organisms transported in suitable containers?			
43	Are genetically modified organisms transported in break proofed and closed containers?			
44	Where risk assessment indicates the animal room and contents will need to be fumigated, is the room capable of being sealed by appropriate means?			

	Note: consideration should be given to the means of removing or extracting the fumigant.			
45	Is there a hygiene plan in place?			
46	Is the animal facility entered via a lock equipped with two self closing doors, hand washing basin, disinfection dispenser and shower?			
47	Does the facility have windows that open?			
48	Does the facility have an emergency power supply for safety relevant equipment such as ventilation system?			
49	Where mechanical ventilation is provided, is the airflow inwards? Note: Air should not be recirculated to any part of the building.			
50	Is the ventilation system designed to prevent accidental back flow and positive pressurization in any part of the animal unit?			
51	In case of work with airborne pathogens, is a negative pressure relative to the pressure of the immediate surroundings should be maintained? Note: Extract air should be HEPA filtered			
52	Are HEPA filters sited in such a way that they are accessible for testing and allow their safe removal? Note: HEPA filters have to be sterilized on site or immediately sealed in an airtight plastic sack for later sterilization			
53	Are animals infected with risk group 3 micro-organisms housed in cages in isolators with ventilation passing through HEPA filtration to the exterior? Alternatively, are animals housed in cages within ventilation units with ventilation exhausts placed behind cages?			
54	Are carcasses sterilized prior to disposal? Note: If this is not possible inside the facility, carcasses have to be transported in closed, leakproofed and disinfected containers			
55	Is waste water has sterilized?			

56	Is the animal unit should be isolated from other buildings?			

B. GREEN HOUSE

	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
57	Is the Greenhouse a permanent structure? Note: The structural design of the greenhouse should be adequate to withstand extreme weather conditions.			
58	Are internal walls, ceilings and floors resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area? Note: All penetrations into these structures and surfaces should be sealed (e.g. cables, pipes) This is an optional requirement			
59	Is contaminated run-off water controlled? This is optional for this level.			
60	Is there a suitable program to prevent plant pests, weeds, insects and rodents?			
61	Are there measures in place to control undesired species such as weeds, insects, rodents, and arthropods?			
62	Are the protective structures in place sufficient to minimise dissemination of genetically modified micro-organisms during transfer of living material between the greenhouses?			
63	Are GMOs transported in suitable closed non- breakable containers?			
64	Is the container decontaminated if organisms outside are present within the effective dissemination distance of the experimental organism?			
65	Is the greenhouse floor made of gravel or other greenhouse-typical material? At least the pavement should be solid, e.g.			

	of concrete.			
66	Is the ground of the greenhouse made of water impermeable material? Note: Gravel and other porous material under the planting tables are suitable if there is only a minor possibility that reproducible biological material can be transmitted through the soil. In this case earth beds are also possible.			
67	If part of the ground consists of gravel, are appropriate treatments made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel?			
68	Is the ground of the greenhouse is made of water impermeable material with provisions to collect and sterilize wastewater?			
69	Does the facility design minimize escape of GMOs?			
70	Are the facility's windows closed and sealed			
71	Are all glazing resistant to breakage?			
72	Is a Biohazard sign at placed at the entry?			
73	Is there a sign posted indicating: (optional) (e) That a restricted experiment is in progress (f) Name of responsible individual (g) Plants (organisms) in use (h) Special requirements for using the area? (a) Note: this requirement is optional for this containment level			
74	Is access limited to the project leader/facility manager and personnel authorized by him?			
75	Are protective clothing worn outside the greenhouse?			
76	Are separate facilities for storing protective and street clothing available?			
77	Is protective clothing sterilized before laundry?			
78	Gloves should be worn at work			
79	Are injuries reported immediately to the			

	project leader?			
80	Are there written instructions for greenhouse practices and procedures?			
81	Does the facility have a hand disinfection apparatus and wash basin?			
82	Is the Greenhouse entered via a lock with self-closing doors and hand disinfection apparatus and touch-free hand washing basin put in place?			
83	Is an air intake screening and motorized or gravity-driven exhaust fan louver in place?			
84	Is the glasshouse held under negative pressure compared to the surrounding?			
85	If there is the danger of the dissemination of airborne pathogens, is exhaust air filtered through HEPA- filters?			
87	Are equipments which were in contact with GMOs sterilized before cleaning, if the contact may lead to the transmission of GMOs?			
88	Is an Autoclave available within the facility?			
89	Is the glasshouse surrounded by a security fence or equal protection system?			

C. LABORATORY ACTIVITIES

	Requirement	**Compliance (√)**		
		Yes	No	*If No, provide reason for non-compliance, what is being taken to rectify the issue; or reason why an exemption is warranted*
	1. Physical control measures **(a) Facility design**			
90	Is the facility dealing with viable micro-organisms separated from the environment (having a closed system)?			
91	Is the laboratory suite isolated from other facilities?			
92	Is there restricted access to the facility (e.g. use of electronic cards, passwords)?			
93	Is the laboratory sealable for fumigation?			

94	Does the facility have windows that open? This is optional for this level.			
95	Is a Biohazard sign placed on the entrance door of the facility?			
96	Is there a sign at laboratory entrance indicating: (a) special hazard signs if an organism containing rDNA needs special provision for persons entering the laboratory (b) names of occupants who have access to the laboratory?			
97	Does the facility have a ventilation system in place? Note: Extract and input air from the laboratory should be HEPA filtered			
98	Is entry into the work area through an airlock?			
99	Does the air lock have two doors which are interlocked?			
100	Is the air lock equipped with a hand washing basin (touch free) and hand disinfectant dispenser?			
101	Is a negative pressure relative to the pressure of the immediate surroundings maintained?			
102	Is the ventilation system alarmed to indicate a failure to generate a negative pressure?			
103	Is the ventilation system connected to an emergency power supply?			
104	Is the switch for ventilation system should be accessible from outside of the laboratory in case of fumigation?			
105	Are all facility penetrations fitted with seals to minimize air leakage?			
106	Does the facility walls, doors and ceilings allow the incursion of insects and pests?			
107	Is the facility drainage exits protected against the entry of invertebrates by the use of screens or any other appropriate means?			
108	Are workbenches, floors, and walls constructed so as to allow easy decontamination and should be resistant			

	to water, acids, alkalis, solvents disinfectants, and decontamination agents?			
109	Is a clearly demarcated section provided for the storage of PPE within the facility?			
110	Is a communication system must be in place to allow contact with others outside the facility e.g. Two-way communication system, networked computer e.t.c.?			
	(b) Containment equipment			
111	Does the facility contain at least one certified Biological Safety Cabinet (BSC)? Note: The choice of the BSC must be appropriate for the work to be performed and should be placed at an appropriate position			
112	Are the facility surfaces easy to clean and resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents?			
113	Is the suitability of the equipments to be used checked prior to installation for safety purposes?			
114	Is the suitability of any chemical disinfectants to be used checked? This is optional for this level.			
115	Is the autoclave installed on site?			
116	Does the autoclave provide a print- out showing the temperature and time of sterilization?			
117	Is there a hand-wash sink, detergent, disinfectant and paper towels in place? (b)			
118	Does the containment facility ensure that there is no leakage or escape of genetically modified organisms? This is optional for this level.			
119	Is the design of waste transport containers appropriate to prevent contamination of the surroundings?			
120	Is the design of containers for the transport of genetically modified organisms inside the facility adequate to prevent escape of the organisms?			

121	Are the laboratory equipments appropriate for the work to be performed and do they prevent the escape of the genetically modified organisms?			
122	Contaminated filters are sterilized onsite and sealed in a plastic bag for later sterilization			
123	Are alarm systems in place for workers working alone?			
124	Do occupants shower before leaving the laboratory?			
125	Is there an observation window or alternative in place so that occupants can be seen? This is optional for this level.			
	2. Safety Management **(a) Work procedures**			
126	Are procedures or activities that may generate aerosols containing GMOs conducted in a certified BSC or other aerosol containment equipment?			
127	Are procedures done in a manner that prevents or minimises aerosol formation?			
128	Are engineering control measures exercised and supplemented with appropriate personal protective clothing and equipment where necessary?			
129	Are equipments adequately tested and maintained (calibration/ certification/ servicing)?			
130	Are doors closed while working?			
131	Do airlock doors remain closed at all times, except when authorised persons are entering or exiting the facility?			
132	Is access to the laboratory restricted when experiments are in progress?			
133	Are workers given adequate information on safety matters and suitably trained? Note: Training should include the following points: (a) the existence and application of written work procedures (b) the procedures for using particular pieces of equipment (a) spillage control and other emergency procedures			

134	Are the process steps at which hazardous quantities of aerosols formed determined? This is optional for this level.			
135	Are genetically modified organisms transported within the facility in closed, robust and leakproofed containers? This is optional for this level.			
136	Are work surfaces decontaminated daily and after a spillage?			
137	Are effective disinfectants and specified disinfection procedures in case of spillage of genetically modified organisms in place?			
138	Are genetically modified organisms in contaminated material and waste inactivated?			
139	Are genetically modified organisms in effluent from the hand washing sinks or drains and showers and similar effluents inactivated?			
140	Does gaseous decontamination of the facility take place: (a) after a spill of viable GMOs outside primary containment (e.g. BSC) and that cannot be decontaminated by another means; (b) prior to suspension, surrender, expiry or cancellation of certification; (c) prior to re-certification of the facility at a lower containment level, if stipulated by the Regulator; and (d) prior to maintenance work on equipment in the facility that cannot be decontaminated by another means?			
141	Are benches free from clutter?			
142	Is the identity of the genetically modified organisms regularly checked to avoid the culturing of incorrect stains? Note: The time between these checks should dependent upon the potential hazard.			
143	In case of an incorrect identity of a genetically modified organism, are there			

	corrective actions in place following the results of the controls and is there a way to register them?			
144	Do laboratory users ensure that the performance of safety equipment is validated? Note: This should include: (f) Certification/calibration of equipment (g) maintenance of the equipment (a) markers used to verify the efficiency of autoclaves			
145	Is mouth pipetting prohibited?			
146	Is eating, drinking, smoking, applying cosmetics prohibited in the work area?			
147	Is skin contact with recombinant DNA material avoided?			
148	Are hands washed after handling recombinant DNA and before leaving the laboratory?			
149	Are protective clothing always worn while working in the laboratory? Note: The following PPE must be worn by all authorised persons in the work area(s): (j) protective clothing to protect the front part of the body (e.g. long-sleeved, back fastening, tight-wristed protective clothing); (k) closed footwear; (l) gloves; (m) eye protection; and (a) waterproof dressings on all broken skin.			
150	Are the protective clothing decontaminated before laundering?			
151	Are the protective clothing and street wear kept separate?			
152	Has an insect and rodent control programme been implemented?			
153	Has the workplace and environmental exposure to any physical, chemical or biological agent been kept to the lowest practicable level?			
154	Have tests, when necessary, for the presence of viable genetically modified organisms outside the primary physical			

	containment been performed?			
155	Has the use of sharps been avoided where possible?			
156	Are contaminated syringes / sharps disposed of in a 'Sharps bin' and incinerated?			
157	Where appropriate, are the personnel vaccinated against the agents to be handled?			
158	Are Institutional Biosafety Committees or sub-committees in place and constituted as per the NBA Contained Use Regulations, 2011?			
159	Are non experimental animals restricted from entry into the laboratory?			
160	Where appropriate, are serum samples taken from workers and stored to provide baseline information in the event of an unexplained illness? Note: this requirement is optional for this containment level			
161	Is sample collection, movement of addition of materials into a containment facility and transfer of viable micro-organisms to another containment facility performed as appropriate?			
162	Is safe storage of biological agents adhered to?			
163	Are non-essential personal effects, including handbags, mobile phones, portable music devices, and other non-essential electronic equipment prohibited in the facility			
164	Is the transport of the GMOs in accordance with the Biosafety (*Handling, Packaging, Storage and Transporting of GMOs Regulations) 2013?*			
	(b) Institutional matters and documentation relating to the safe handling of genetically modified organisms			
165	Is there a copy (electronic or paper) of the Biosafety facility manual available? Note: The Biosafety facility manual must document the following: (a) the contact details of the facility manager			

	(b) a list of persons authorized to use the facility (c) the persons to contact in case of an emergency (d) the layout and operation (including design limits) of the facility (e) details of all organisms being handled in the facility, the risks associated with the use of these organisms, and the management strategies for these risks (f) the procedures that must be followed by all persons entering and exiting the facility, including the use of PPE including the donning and doffing off procedures (g) the procedures for the operation and use of the BSC (if applicable) and any other specialized aerosol containment equipment (h) the assessment of and the procedures for the use of sharps (if allowed) (i) the procedures for the use of normal and emergency communication systems (j) the procedures for the movement of all equipment into and out of the facility, including decontamination (k) the procedures for decontamination of GMOs, including operation and use of the autoclave (l) the procedures for waste and effluent disposal, including transport procedures (m) the procedures for the transport of GMOs within the facility, including for storage of GMOs (n) the procedures for the transport of GMOs outside the facility (e.g. transport to another BSL-1 facility) as outlined in the Biosafety (*Handling, Packaging,*			

	Storage and Transporting of GMOs Regulations) 2013 (o) the procedures for carrying out risk assessment (p) the procedures for training of new staff (q) health assessment of laboratory workers (i)			
166	Are equipment operation and troubleshooting manuals placed within the facility?			
167	Is there a hygiene plan in place?			
168	Are written standard operating procedures provided where appropriate to ensure safety?			
169	Is there a documentation of the appointment of the Biosafety Officer (BSO)?			
170	Has a project leader been appointed?			
171	Is a description of the tasks of the Biosafety Officer (BSO) with respect to safety; internal control; accident/incident; response and preparedness; internal counseling, advice and education; and, reporting in place?			
172	Is there a description of the tasks of the project leader available with respect to: (a) everyday management (b) drawing-up and executing work-protocol?			
174				
176	Have the following documents been centrally held within an institution undertaking contained use?: (a) a paper copy of the Biosafety facility manual (b) records that cover any sites for storage of genetically modified organisms outside of containment facilities (c) records of internally organized inspections (d) records of accidents, including evaluation and any remedial action (a) a list of other data and documents			

	that are held at other locations within the institution?			
177	Are the following documents available? Note: They could be held separately from the main records (see section 176 above): (a) records of staff involved in contained use facilities indicating their experience and training in Biosafety and the type of projects in which they have been employed (b) results of procedures for checking the purity and identity of the genetically modified organisms (c) results of the testing of laboratory equipment (e.g. autoclaves) (d) a list of stored genetically modified organisms for each storage facility (a) work protocols for particular experimental procedures?			
	Contingency plans			
178	Do contingency plans ensure the protection of the environment and the public outside of the facility?			
179	Are emergency response plans, including the procedures and use of specialized equipment required for responding to the following in place?: (i) spills of GMOs in the facility (both inside and outside BSCs) and spills while transporting GMOs outside the facility (ii) accidental exposure to GMOs used within the facility, including procedures for the management and treatment of persons suspected to be infected or contaminated with or exposed escape of animals containing GMOs within the facility (iii) alarms for fire or loss of pressure (iv) loss, theft or unintentional			

	release of GMOs from the facility (v) failure of power or ventilation systems (vi) fire and natural disasters (vii) medical emergencies or serious injury to persons within the facility (viii) security threats other life-threatening situations?			
180	Are there written procedures present for: (a) internal notification of incidents (e.g. spillages) (b) external notification in case of serious risk (c) accident response (measures, reporting, evaluation) (d) emergency preparedness actions and counter-measures in case of accidents or incidents?			

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