

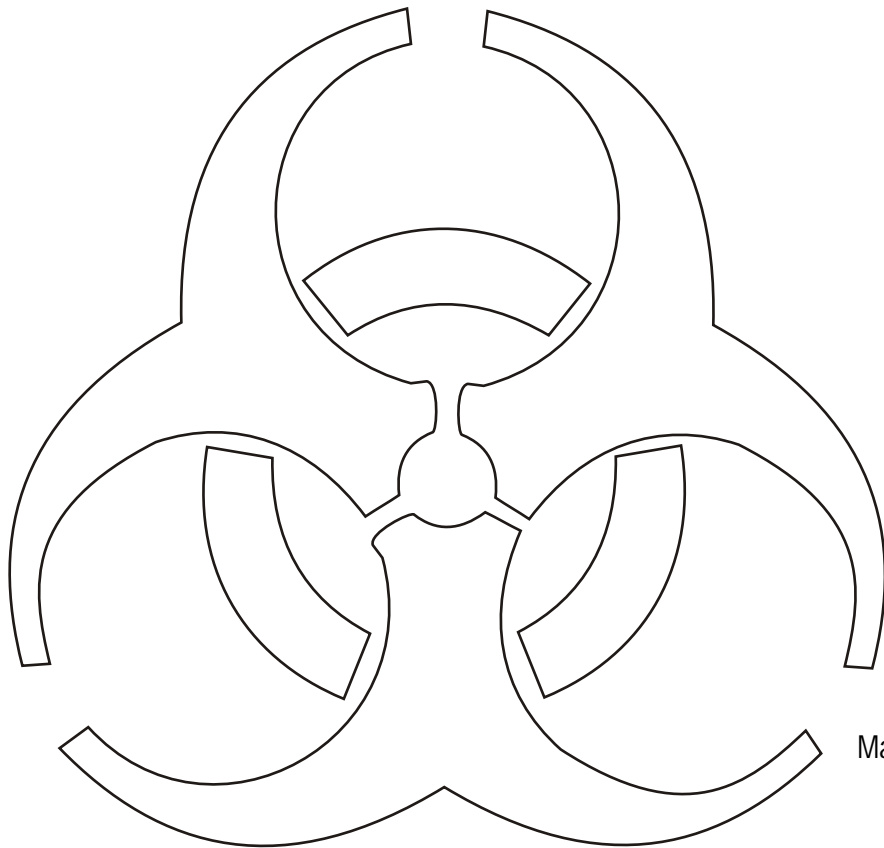
National Guidelines for Containment:

For Regulation of Research with Genetically Modified Organisms and Microbes



May 2007

National Guidelines for Containment: For Regulation of Research with Genetically Modified Organisms and Microbes



May 2007

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Email to: uncst@starcom.co.ug

UNCST 2007

Preface

All over the world, it is recognized that biotechnology (which in simple terms refers to a variety of techniques involving living organisms as a means of production), along with information technology, will drive economic development in the 21st century. In Uganda, the Government has embraced biotechnology as a strategy to enhance agricultural productivity and industrialization, improve health care delivery and preserve the environment. Although biotechnology is beneficial for economic growth and social well-being, it has inherent risks because it involves working with potentially harmful substances or production of unfamiliar genetically modified organisms. Therefore, ensuring biosafety in the application of biotechnology is paramount. It is for this reason that these Guidelines for Containment of Genetically Modified Organisms and Microbes in Research are developed.

In biotechnology, genes from one species may be introduced into other species or organisms, thereby producing transgenic organisms with unique characteristics. Usually, such organisms are new and there may be limited knowledge about their potential effects on human health and the environment. As such, the application of biotechnology should be guided in a judicious manner, so that potential risks are minimized and benefits maximized. In order to achieve this, an assessment of safety of the new genetically modified organism must be done in a closed and controlled facility, or in other words, under “Containment”. Containment broadly describes work with genetically modified organisms and microbes in the laboratory, green or screen houses where escape of such organisms to the environment and/or contamination of said organisms are prevented.

These Guidelines seek to assist establishment and maintenance of containment facilities in order to ensure safety in biotechnology research and development. The Guidelines also outline the regulatory requirements for containment of genetically modified plants and animals intended for research in Uganda. These Guidelines are not intended to substitute any existing or future legal requirements pertaining to the use of genetically modified organisms in Uganda; rather they are complimentary and should be used within the confines of the laws of Uganda.

Additional information on these Guidelines can be obtained from the Uganda National Council for Science and Technology (UNCST). Users who detect errors of omission or commission are encouraged to send their comments to the Executive Secretary of the UNCST.

Dr. Peter Ndemere

Executive Secretary
Uganda National Council for Science and Technology (UNCST)



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Definitions

Allergenicity:	This is a non-toxic, immune system mediated, undesired reaction of the body to a substance or agent.
Application:	All the documentation and other information that may be required by the NBC for the submission of a request for biosafety approval to conduct research.
Applicant:	A party submitting an application for a containment research. Typically, the Applicant is the same as the Authorized Party (see), or is acting in collaboration with the Authorized Party.
Biosafety:	The safe development, transfer and application of biotechnology and its products.
Biotechnology:	Any technique that uses living organisms or substances there from to make or modify a product, improve plants or animals, or microorganisms for specific uses.
Containment:	Safe methods for managing infectious agents or hazardous compounds in a facility where they are being handled or maintained in order to prevent their escape outside the prescribed spaces.
Devitalization:	To diminish or destroy the strength or vitality of something.
DNA:	Deoxyribonucleic acid is one of two types of molecules that encode genetic information. The other is RNA.
Environment:	Land, air and water and living organisms supported by any of those media, including any physical, biological or chemical elements of any of the above.
GMO:	Genetically modified organism, an organism produced through Recombinant DNA (rDNA) technology involving the introduction of a section of DNA from a “donor” organism to a “recipient” organism.
Hazard:	Any harmful/adverse effect on human health and /or environment

Modern Biotechnology:	This involves intentional manipulation of genes, cells and living tissue, such as genetic engineering, tissue/cell culture.
Organism:	A biological entity capable of replication or transferring genetic material.
Pathogenicity:	Indication of whether an organism e.g. bacteria, fungus or virus is able to cause a disease to plants, animals or humans.
Recombinant DNA:	DNA which has been altered by joining genetic material from two different sources. It usually involves putting a gene from one organism into the genome of a different organism.
Recombinant DNA technology:	Techniques for cutting apart, splicing together, and producing pieces of DNA from different sources.
Release:	Escape from the constraints of physical containment that are found in a laboratory, greenhouse or other contained structure.
Risk:	A function of the probability of harm and the severity of that harm, consequential to the transport, handling or use of an organism.
Toxicity:	This means poisoning. The toxicity of a substance is mostly given as an LD50 for vertebrates in weight units per kilogram body weight.
Traditional Biotechnology:	This technology uses whole living organisms to cause change for example use of special bacteria during cheese and yogurt making.

The National Guidelines for

Containment

For Regulation of Research with
Genetically Modified Organisms
and Microbes

Chapter 1. Introduction

Chapter 2. Regulatory Procedures

Chapter 3. Biosafety Procedures

Chapter 4. Operating Procedures

Chapter 5. Design of Containment Facilities

Chapter 6. Commissioning, Certification and Recertification

Selected References

Chapter 1

Introduction

Biotechnology, both traditional and modern is today generally accepted to contribute substantially to sustainable development by generating improvements in the fields of agriculture, industry, health care (human and animal) and environmental protection. Traditional biotechnology has been in use for centuries notably in the brewing and fermentation industries and in the production of animal vaccines. Modern biotechnology, however, includes, among other technologies, cell and tissue culture, monoclonal antibodies, recombinant DNA (rDNA) technology, genetic engineering and nanotechnology. The increased precision in modern biotechnology makes these new techniques particularly attractive.

The development of new techniques of genetic modification in the early 1970's introduced a new dimension to biotechnology. Scientists can now combine DNA from different organisms, giving rise to Genetically Modified Organisms (GMOs) also referred to as Living Modified Organisms (LMOs). Genetically Modified Organisms are produced through Recombinant DNA (rDNA) technology involving the introduction of a section of DNA from a “donor” organism to a “recipient” organism. The genome of the recipient organism is, therefore, modified.

While recognizing the potential benefits of this new molecular technique which allows a greater diversity of genes to be introduced into organisms, the relative lack of familiarity with such modified organisms and the gaps in knowledge regarding the effects of the interaction of these GMOs with the environment, make it necessary to institute measures to ensure that the technology is developed in a precautionary and judicious manner. Therefore, results of this modification need to be assessed for risks to human health, conservation of biodiversity and the environment before the intentional release of the modified organism. This involves assessment of the modified material under containment.

During genetic modification for desired traits, handling of infectious microorganisms is a common practice and this is a source of infection, including mortality among laboratory workers. Moreover, there have been reported incidents of secondary transmission of disease to the public at large, which may be due to possible contamination of the environment or personnel. Laboratory workers can minimize the risks associated with work involving these infectious agents through the application of appropriate biosafety and containment principles and practices.

Containment describes the safe methods for managing infectious agents or hazardous compounds in the laboratory, greenhouse and screen-house environment where they are being handled or maintained in order to prevent their escape outside the prescribed containment spaces. The purpose of containment is to reduce contamination of the test material and/or exposure of containment facility workers, other persons and the outside environment to potentially infectious or hazardous agents. There are two types of containment, physical and biological containment, and both are addressed by these *Guidelines*.

In recognition of the tremendous benefits of modern biotechnology and the possible risks thereto, these *Guidelines* seek to assist relevant stakeholders in the establishment, maintenance and management of national and institutional containment capacities that provide safety in biotechnology research for development. These *Guidelines* are, therefore, intended to provide in addition a clear and concise summary of the regulatory requirements governing contained research that involves genetically modified (GM) plants and animals in Uganda. The *Guidelines* were developed in accordance with the National Biosafety Policy administered by the Uganda National Council for Science and Technology (UNCST). Supporting documents and guidance shall be published by UNCST and made available on its website (<http://www.uncst.go.ug>), which should be consulted by Applicants and Authorized Parties. In the event that a conflict or inconsistency arises between these *Guidelines* and the terms or conditions of a more specific document provided by UNCST or the National Biosafety Committee (NBC) for accomplishing the purposes of these *Guidelines*, the Terms and Conditions of such document will govern.

1. Need for the Guidelines in Uganda

Uganda together with 168 countries adopted Agenda 21 and the Convention on Biological Diversity (CBD) at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil in 1992. Both Agenda 21 and the CBD while recognizing that biotechnology is essential for the attainment of conservation and sustainable use of biological diversity, particularly by and for improvements in agriculture, food and feed production and supply, health care and environmental protection, cautioned that its development and application be pursued judiciously.

In particular, the CBD in Article 8(g) encourages Parties to the Convention to “establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which is likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity also taking into account risks to human health”.

Article 19(3) of the CBD calls upon “Parties to consider the need for and the modalities of a protocol setting out appropriate procedures, including in particular, Advance Informed Agreement (A.I.A) for the safe transfer, handling and use of any LMOs resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity”. “Article 19(4) makes it obligatory for Parties to directly or indirectly provide available information about the use and safety regulations required by these Parties in handling such organisms as well as any available information on the potential adverse impact of the specific organism to the receiving Party”.

To facilitate the implementation of the aforementioned objectives, Uganda participated in the negotiation and drafting of the Cartagena Protocol on Biosafety with specific focus on trans-boundary movement of any LMOs/GMOs resulting from modern biotechnology that may have adverse effects on the conservation and use of

biodiversity and the adoption of appropriate procedure for A.I.A. Uganda signed the Cartagena Protocol in May 2000 during the 5th Conference of Parties in Nairobi, Kenya.

2 Purpose

The *Guidelines* seek to facilitate the development and enhancement of national capacities to identify, assess and manage potential risks, and establish codes of practice for containment of GMOs in research. These would be achieved through the following objectives:

Develop robust processes and define precise procedures in order to maintain material and genetic confinement in the handling of GMOs, which will build trust and confidence in the public-at-large regarding GMOs

Provide measures for risk assessment and evaluation in all operations involving GMOs or any other processes of biotechnology, including but not limited to the prescription of appropriate conditions for the use of biotechnology and its products.

Promote opportunities for the application and exploitation of innovative biotechnology products for the general well being of humanity.

3 Target Groups

The safe conduct of experiments involving rDNA depends on the individual conducting such activities. In addition to the development of good laboratory practices and procedures and the training of individuals in these elements, motivation and good judgment are also key essentials. These *Guidelines* are, therefore, intended to assist the National Biosafety Committee (NBC), Institutional Biosafety Committee (IBC), Biological Safety Officer (BSO), the Principal Investigator (PI), containment facility staff, and research scientists in determining safeguards that should be implemented.

3.1 The National Biosafety Committee (NBC)

The National Biosafety Committee is the national technical arm of the UNCST on matters concerning biotechnology and biosafety, and derives its legal status from the UNCST statute No. 1 of 1990. The committee provides technical advice on biosafety to government and maintains links with biotechnology institutions through IBC's. The NBC reviews biotechnology research proposals involving especially high-risk category organisms and controlled field experiments, and recommends the appropriate type of containment facility. The committee approves and monitors deliberate release of genetically engineered organisms.

3.2 The Institutional Biosafety Committee (IBC)

Any institution where research involving GMOs or infectious microbes is conducted is required to appoint an Institutional Biosafety Committee. The committee is to consist of at least five persons who must be citizens of Uganda, two of whom are not affiliated with the institution. The IBC reviews GMO research programs or proposals and confirms the PI's assignment of the

appropriate containment level for the proposed work. Initially, the IBC considers the proper containment level for the unmodified organism, and then decides whether or not the proposed change to the organism could increase, decrease, or leave unchanged the organism's necessary containment level. The Committee ensures compliance with the National *Guidelines* by evaluating facilities, procedures, and the expertise of personnel involved in the research. In addition, the IBC is responsible for adopting emergency plans for responding to an accidental release from containment. To facilitate timely disposal of residual transgenic experimental materials, the IBC may adopt a closeout policy that provides the PI with written notice of project termination dates. The Committee is responsible for maintaining and/or verifying documentation of GMO research at the institution, and acts as a point of contact for the NBC and other agencies. The Committee is also responsible for ensuring that all rDNA research conducted at or sponsored by that institution is conducted in compliance with these *Guidelines*.

3.3 Biological Safety Officer (BSO)

For institutions conducting GM research on organisms that require special containment conditions at levels BL2, BL3 or BL4 (see Section 3.2), or large-scale microbial research, must appoint a Biological Safety Officer. This person automatically serves as a member of and secretary to the IBC, act as a technical liaison between researchers and the IBC, develops emergency plans, and periodically inspects facilities and protocols. Because higher containment levels require more scrutiny, the BSO serves as regular contact between the IBC and the NBC.

3.4 Principal Investigator (PI)

The PI is ultimately responsible for the research project and for ensuring compliance with biosafety standards. The PI functions as a project manager as well as a researcher, bearing responsibility for training and supervising personnel according to the National guidelines and to the satisfaction of biosafety committees, communicating with the IBC, BSO, greenhouse/screenhouse manager and staff, and correcting any operations that may result in a loss of containment. Based on the nature of the GMO, the PI determines the proper containment level for the project and, in accordance with the National Guidelines, develops the necessary experimental protocols; and subsequently submits this information to the IBC for review.

The PI must file a notification document with the IBC for all intended GMO experiments. Notification is made either before or at the time the work is initiated, depending on the level of containment required. The IBC may require the PI to provide complementary information before initiation of the research.

3.5 Facility Staff

Facility staff may range in experience from research scientists, technicians, part time workers and students working in the laboratory, greenhouse or screen-house. Regardless of individual duties, all staff should be appropriately

trained in the processes and procedures of handling GMOs and microbes, in particular focusing on any differences between caring for GMOs and conventional plants, or any organisms that may affect their own work.

In fulfillment of the above, all staff must undergo an orientation session to learn about the nature of the GMO and any special practices to be employed when handling or working around them. For example, where GM microbes are being tested for their ability to associate with plant roots, the PI may require that runoff from watering is collected and treated prior to disposal. Both the facility manager and the PI should work with the staff to ensure compliance with safety procedures and standards.

3.6 Inspectorate

Inspection is part of ensuring biosafety when handling GMOs and microbes. These guidelines provide for inspection right from the time of establishment of a containment facility. The different inspection agencies of relevance in this case include the NBC (section 1.3.1), the ministry responsible for Agriculture and Environment Authority as well as any other agencies authorized by UNCST. The agencies mandated to undertake inspection will use these Guidelines during their routine biosafety inspection of the containment facilities and activities.

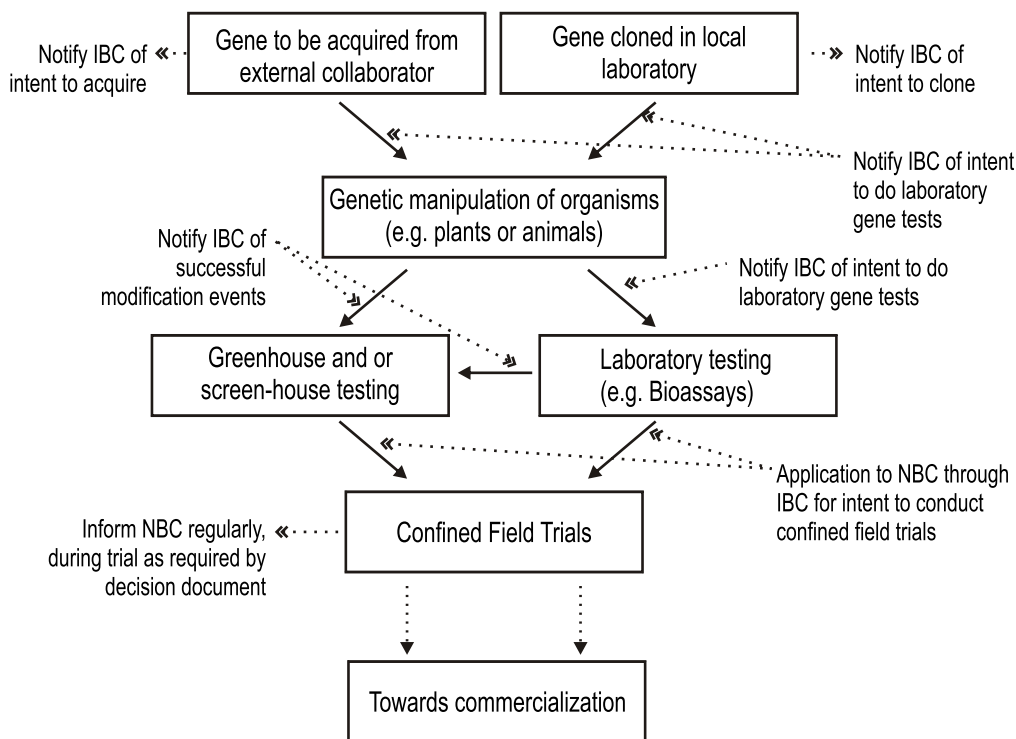
Chapter 2

Regulatory Procedures

GMOs are subject to National Guidelines and regulations pertaining to their containment, movement and release into the environment. Institutions where biotechnology research is conducted are required to have an institutional biosafety committee (IBC) serving as the local authority. UNCST avails a Notification Form (Appendix 1) to be completed by Applicants intending to carryout GMO research and is also available on the UNCST website (www.uncst.go.ug). Submission of the Notification shall be through the Institutional Biosafety Committee (IBC), whose officers must ensure completeness of the application form and verify availability of the proposed facilities before endorsing and forwarding the application to UNCST. The Notification after scrutiny and clearance by the IBC shall be submitted by regular mail, courier, or electronically to:

National Biosafety Committee (NBC) Secretariat
 Uganda National Council for Science and Technology
 P.O. Box 6884 Kampala, Uganda
 Telephone: +256-41-705500
 Fax: +256-41-234579
 Email: uncst@starcom.co.ug
 Website: <http://www.uncst.go.ug>

Figure 1. Regulatory steps in developing GMOs in Uganda



Chapter 3

Biosafety Procedures

1. Risk Assessment

Risk assessment is a critical step in the selection of an appropriate containment level for research. Risk assessment should be conducted to determine which biosafety level (See Section 3.2) is required when working with infectious agents or whole animals/plants whose genome has been altered by stable introduction of recombinant DNA, and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals/plants. Individuals with varying expertise and responsibilities should be included in the risk assessment process and can include, among others, the facility Director, laboratory supervisor, PI, microbiologist, BSO and other designated members of the biosafety committees.

Risk assessment is performed on a case-by-case basis. The risk assessment procedure consists of three subsequent steps:

- a. Identification of potentially hazardous characteristics (pathogenicity, toxicity, allergenicity, invasiveness etc).
- b. Determination of circumstances under which the organisms can be handled safely.
- c. Determination of the Risk Group.

The Biosafety level required for work with a particular agent is based on the manipulations generally associated with laboratory scale research procedures. If a particular procedure, such as preliminary identification, poses a lower hazard than manipulation of a live culture, then a lower containment level may be appropriate. On the other hand, a higher level of containment may be required if the risk assessment indicates that the procedures pose a higher risk than routine laboratory scale and diagnostic manipulations. These factors have been taken into consideration to classify infective microorganisms, plants and animals into risk groups and related biosafety levels (Table 1 and 2) (WHO, 2004). A list of infective microorganisms to human in the different risk groups is provided in Appendix 3 (USDHHS/NIH, 2002).

Table 1. Classification of infective microorganisms, plants and animals by risk group (WHO, 2004, Traynor *et al.*, 2001)

Risk Group	Description
Risk Group 1	<p>A microorganism that is unlikely to cause human or animal disease.</p> <p>Plants that are not noxious weeds or cannot cross with weeds.</p> <p>Stock animals after quarantine and animals that are deliberately inoculated with microorganisms belonging to Risk Group 1</p>
Risk Group 2	<p>A microorganism that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.</p> <p>Plants that are noxious weeds or can interbreed with weeds but would have a negligible impact or could be readily managed. Plants containing genomes of non - exotic infectious agents.</p> <p>Animals that are deliberately inoculated with microorganisms belonging to Risk Group 2.</p>
Risk Group 3	<p>A microorganism that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.</p> <p>Plants infected with exotic infectious agents capable of causing serious environmental harm. Plants containing vertebrate toxin.</p> <p>Animals that are deliberately inoculated with microorganisms belonging to Risk Group 3.</p>
Risk Group 4	<p>A microorganism that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.</p> <p>Plants involved in experiments on readily transmissible exotic infectious agents that are potentially serious pathogens to major crops, and are performed in the presence of their arthropod vectors</p> <p>Animals that are deliberately inoculated with microorganisms belonging to Risk Group 4</p>

Table 2: Relation of risk groups for microorganisms, plants and animals to biosafety levels, practices and equipment*

Risk Group	Biosafety Level	Laboratory Practice and Equipment
1	BL1	GLP and open bench work. Limited access, protective clothing and gloves.
2	BL2	GLP plus protective clothing, biohazard sign, BSC for potential aerosols. Decontamination of waste and cages before washing.
3	BL3	As Level 2 plus special clothing, controlled access, directional airflow, BSC and/or other primary devices for all activities. Special protective clothing for all activities.
4	BL4	As Level 3 plus airlock entry, shower exit, special waste disposal, Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air.

GLP- Good Laboratory Practices; BSC - Biological Safety Cabinets

*Risk groups can be related but not "equated" to the biosafety levels.

Source: WHO, 2004

2. Biosafety Levels

Biosafety levels (BL) are selected to provide the end-user with a description of the minimum containment required for handling the organism safely in a laboratory setting.

2.1 Biosafety Level 1 (BL1)

This applies to the basic laboratory and facilities that handle organisms that cannot spread rapidly and are not known to have any negative effects and if accidentally released, would not pose any environmental risk (e.g. *Escherichia coli* and *Agrobacterium* spp). It also applies to plants genetically modified with genes from the same species for example an experiment designed to study transgenic potato plants containing cloned genes for insect resistance obtained from primitive potato cultivars. BL1 is also suitable for the maintenance of most stock animals after quarantine and for animals that are deliberately inoculated with microorganism belonging Risk Group 1.

BL1 requires no special design features beyond those suitable for a well-designed and functional laboratory and facilities. Biological safety cabinets (BSCs) are not required. Work may be done on an open bench top, and containment is achieved through the use of good laboratory practices.

2.2 Biosafety Level 2 (BL2)

This applies to the laboratory and facilities that handle organisms that could be viable in the surrounding environment but would have a negligible impact or could be readily managed. The primary exposure hazards associated with organisms requiring BL2 are through the ingestion, inoculation and mucous membrane route. Agents requiring BL2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands) or splashes. BL2 is required for transgenic plants that may exhibit weedy characteristic or that may be capable of interbreeding with weeds. For example, greenhouse tests of transgenic sunflower containing wheat genes intended to confer resistance to the fungus *Sclerotinia* because sunflower is capable both of hybridizing with wild relatives, and becoming established as a volunteer weed. BL2 containment is assigned to transgenic experiments that use the entire genome of non-exotic infectious agents. This level of containment is also appropriate for experiments of animals that are deliberately inoculated with microorganisms belonging to Risk Group 2.

Primary containment devices such as BSCs and centrifuges with sealed rotors or safety cups are to be used as well as appropriate personal protective equipment (i.e., gloves, laboratory coats, protective eyewear). Environmental contamination must be minimized by the use of hand-washing sinks and decontamination facilities (autoclaves).

2.3 Biosafety Level 3 (BL3)

This is designed to prevent the accidental release of transgenic plants, animals or microorganisms that have a recognized potential for significant detrimental

impact on the environment. These organisms may be transmitted by the airborne route, often have a low infectious dose to produce effects and can cause serious or life-threatening disease. BL3 applies to plant research that involves exotic infectious agents capable of causing serious environmental harm or transgenic plants containing genes from an exotic infectious agent in which a complete functional genome of the infectious agent could possibly be reconstituted. Experiments using transgenic plants or organisms that contain genes coding for vertebrate toxins should be conducted in BL3. For example inoculation of transgenic groundnut plants that contains fungal resistance genes with *Aspergillus flavus*, the organism responsible for producing the potent vertebrate mycotoxin, aflatoxin. BL3 is also suitable for works with animals that are deliberately inoculated with agents belonging to Risk Group 3, or when otherwise indicated by a risk assessment.

BL3 emphasizes additional primary and secondary barriers to minimize the release of infectious organisms, plants and animals into the surrounding environment. Additional features to prevent transmission of BL3 organisms are appropriate respiratory protection, HEPA filtration of exhausted laboratory air and strictly controlled laboratory access.

2.4 Biosafety Level 4 (BL4)

This is the maximum containment available. This level is recommended for experiments involving certain exotic, readily transmissible infectious agents that are potentially serious pathogens and that are performed in the presence of their arthropod vector. For example, an experiment to test the efficacy of the African cassava mosaic virus coat protein to protect cassava plants against infection by that virus would necessitate use of a whitefly vector, *Bemisia tabaci*, in challenge inoculations. This devastating virus is not found in Uganda, however the vector is present, therefore, and such an experiment poses a significant risk should the virus or vector escape the containment facility. BL4 is also suitable for organisms that have the potential for aerosol transmission, often have a low infectious dose and produce very serious and often fatal disease; there is generally no treatment or vaccine available. Housing areas for animals infected with Risk Group 4 agents must also maintain the criteria for maximum containment described for BL4.

This level of containment represents an isolated unit, functionally and, when necessary, structurally independent of other areas. BL4 emphasizes maximum containment by complete sealing of the facility perimeter with confirmation by pressure decay testing; isolation of the researcher from the pathogen by his or her containment in a positive pressure suit or containment of the pathogen in a Class III BSC line; and decontamination of air and other effluents produced in the facility.

3. Spread of Organisms

a. Natural routes of infection

All Pathogens have their own modes of transmission, by which they spread from one host organism to another. The important routes of infection include skin contact, air or aerosols, pricking (insects or needles), blood-blood contact, wounds, faecal material and mouth.

Aerosols are very small droplets of fluid that can spread through the air. They are formed during activities such as pouring fluids, falling droplets, blending, opening wet caps, centrifugation by means of open tubes, emptying a pipette by blowing, or heating a wet inoculation in a flame. The formation of aerosols should be avoided as much as possible by performing aerosol-producing activities in a safety cabinet.

b. Routes of contamination

Any open source of organisms (for instance an open petri-dish) may lead to contamination. To minimize contamination, a container holding infectious agents or GMOs should be opened in sterile surroundings for instance close to a Bunsen burner or in a safety cabinet.

c. Undesired spread of organisms or genetic material

Spread of organisms or genetic material to the environment is often undesired, since it may involve the dissemination of pathogens or toxins, or lead to the disruption of ecological balances. This is undoubtedly true when dealing with organisms belonging to risk groups 2, 3 and 4. However, even the spread of risk group 1 organisms, which present minor risk, should be limited.

d. Bacteria, yeasts and fungi

Bacteria are often capable of transferring genetic material. This is especially the case when vectors are used that are self-transmissible. To avoid genetic material from being easily transferred, vectors are that are difficult to mobilize, or non-mobile are usually used.

e. Viruses

A distinction can be made between wild type viruses and viral vectors (constructions derived from viruses). The use of viruses or viral vectors always implies the use of host cells. Without host cells, virus cannot be replicated. The ability to spread or replicate may differ from one virus to another. Some viral particles are able to spread through the air or to survive for very long periods of time. Other viruses, such as HIV, are extremely vulnerable outside their host. Plant viruses sometimes need vectors to be able to spread. These vectors are often insects that suck up the virus and spread it to other plants.

f. Animal and human cells

Animal and human cells cannot easily spread to the environment. However, there are cells that are specially designed to survive in non-sterile surroundings, such as fish or frog eggs. Genetic material of animal or human can only be spread to

the environment when the cells involved are infected by biological agents, such as viruses, that are able to mobilize their genetic material. From a biosafety point of view, the question whether or not cells are infected by biological agents is very important.

g. Transgenic plants

When transgenic plants are grown in containment facilities, their spread is greatly curtailed and are highly likely not to spread at all. Nevertheless, the undesired spread of transgenic plants deserves special attention. If no proper containment measures are taken, pollen may be disseminated to the environment through the air or aided by insects. Whether or not this presents a genuine risk, depends on how the plant reproduces: by self-pollination or by cross-pollination. Where a cross-pollinator is involved, it should be carefully checked whether any of its wild relatives, which it might successfully hybridize with, is growing in the vicinity. Seeds originating from transgenic plants may also easily be disseminated in the environment especially when they are very small or sticky as they will very likely be accidentally taken along by persons leaving the containment facility. Some plant parts may also grow and turn into whole new plants themselves. These reproductive parts of plants should not be discarded without destroying them properly. This is why containment facility staff handling transgenic plants or plant material should pay special attention to the possible spread of plant parts that are still able to reproduce. To avoid undesired spread to the environment, all reproductive parts of transgenic plants should be destroyed before they are discarded as waste.

h. Transgenic animals

The unwanted spread of transgenic animals should be prevented. Small rodents, like mice, should be kept in appropriate cages and the animal houses should be designed in such a way that it is impossible for the animals to escape. When a genetically modified micro-organism or a wild-type pathogen is administered to the animal, it should be determined on a case-by-case basis how to prevent the micro-organism from spreading. It may be necessary to keep the animals in individually ventilated cages, and to inactivate all materials that have been in contact with the animals. When cells or other biological material are used in animals, it should be taken into account that viruses may be present in this material. If viruses are present, then containment measures taken will depend on the virus' risk group.

4. Containment

Containment is the practice of preventing unwanted/unintended release of experimental organisms into the environment or exposure of facility workers to these potentially harmful organisms. It is accomplished through a combination of management practices, physical barriers, and biological methods intended to prevent GMO transfer or survival. Physical containment conditions within laboratories and other research facilities may not always be appropriate for all organisms because of their physical size, the number of organisms needed for an experiment, or the

particular growth requirements of the organism. Likewise, biological containment for microorganisms may not be appropriate for all organisms, particularly higher eukaryotic organisms. However, significant information exists about the design of research facilities and experimental procedures that are applicable to organisms containing rDNA that is either integrated into the genome or into microorganisms associated with the higher organism as a symbiont, pathogen, or other relationship

a. Physical Containment

Physical containment refers to the use of special buildings, equipment and procedures to prevent the unintended release of organisms thereby preventing the exposure of laboratory personnel and environment to the hazardous/harmful agents. The objective of physical containment is to secure organisms containing GMOs and to reduce the potential for exposure of the facility worker, persons outside of the facility, and the environment to organisms containing GMOs.

Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Four levels of physical containment, designated as BL1, BL2, BL3, and BL4 have been described above (section 3.2).

b. Biological Containment

Biological processes can provide a highly effective means of preventing unintended transmission of genetic material. In consideration of biological containment, the vector (plasmid, organelle, or virus) for the GM and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which is to provide biological containment shall be chosen or constructed so that the following types of "escape" are minimized: (i) survival of the vector in its host outside the laboratory, and (ii) transmission of the vector from the propagation host to other non-laboratory hosts.

c. Combining Physical and Biological Containment

A combination of both biological and physical containment measures offers two advantages when planning how to achieve a specified level of containment. First, combining methods reduces the physical requirements to those of the next lower biosafety level. Second, the ability to do BL2 research in an existing BL1 facility may be achieved simply by incorporating biological containment practices. For example an experiment of transgenic cotton located where wild cotton is endemic and found within the isolation distance requires BL2 containment but physically removing all wild cotton within the isolation distance allows BL1 facility to be used.

5. Biosecurity

While biosafety deals with all aspects of containment to prevent any exposure to and accidental release of GMOs, biosecurity is implemented to prevent the theft, misuse or intentional release of GMOs or pathogens without authority. A primary component to a biosecurity programme must be a detailed risk assessment followed by a contingency plan. The biosecurity risk assessment should review and list the relevant

assets, define the threats, outline the vulnerabilities, and determine the countermeasures or mitigation strategies specific for each facility. The biosecurity plan should then address the following factors: physical protection; personnel suitability/reliability; security-specific training; GMO/pathogen accountability; and related incident and emergency response.

Biosecurity precautions should become a routine part of laboratory work, just like aseptic techniques and other safe microbiological practices. Laboratory biosecurity measures should not hinder the efficient sharing of reference materials and related information nor unduly interfere with the day-to-day activities of scientific personnel or be an impediment to conducting research.

Chapter 4

Operating Procedures

Given below is a summary of operating procedures but a detailed outline of generic information that can be used to develop both standardized and more specific operational practices for the different biosafety levels is also provided in Appendix 2.

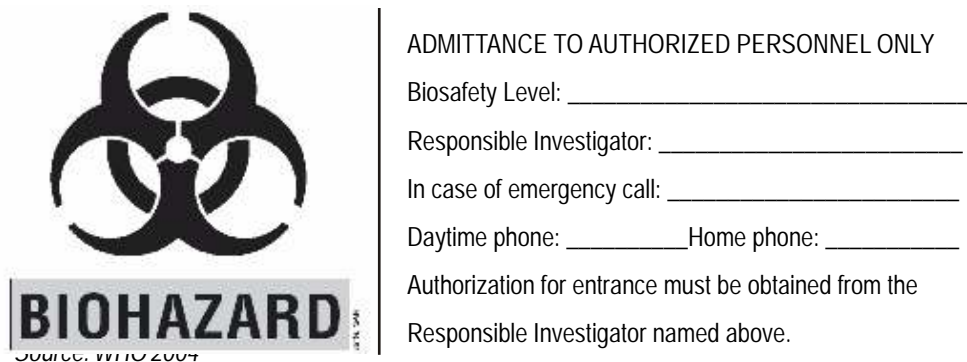
1. Access

Access to laboratories and facilities handling GMOs or infectious agents is restricted, regardless of the biosafety level. At BL1 and BL2, access is restricted at the discretion of the facility manager or PI when experiments are in progress. At BL3 and BL4, the manager, in consultation with the PI should determine access authorization on an individual basis. At BL3 and BL4, a facility staff should accompany maintenance personnel and visitors. An entry and exit logbook is required at BL4 to provide details of names, dates and times of entry and exit by each individual.

2. Signs

No special signs are required for BL1 containment facilities. Entryways into BL2 and higher facilities should be posted with signs indicating that access is limited to authorized personnel only. The internationally recognized biohazard warning symbol and sign (Figure 2) must be displayed on doors of rooms handling organisms classified as BL2 and above. If the experiment uses organisms that pose a risk to the local ecosystem or agriculture, a sign stating so must be placed on the access doors to the laboratory and research facilities. A description of the potential risk may be posted on the restricted access sign as long as this is not confidential information. Experimental materials and chemicals within the facility must also be marked with appropriate signs.

Figure 2. Biohazard warning sign for laboratory doors



3. Disinfection, Sterilization and Hygiene

A basic knowledge of disinfection, sterilization and hygiene is crucial for biosafety in the laboratory and research facilities. The specific requirements for decontamination for biosafety will depend on the type of experimental work and the nature of the infectious agent(s) being handled. Procedure of application of disinfectants varies with material and manufacturer. Therefore, usage should follow manufacturers' specifications.

Pre-cleaning, to remove dirt, organic matter and stains, is essential to achieve proper disinfection or sterilization. Disinfection can be done using chemical germicides, such as chlorine, formaldehyde, phenolics, ethanol/alcohol and hydrogen peroxide. Heat is the most commonly used method of sterilization. "Moist" heat is most effective when used in the form of autoclaving. Dry heat can also be used for sterilization.

4. Handling and Transfer of Materials

Handling and transfer of GM materials or infectious agents for levels BL2-4 should be done in non-breakable containers. For BL3 and BL4 containment, additional sealed secondary container for movement of experimental materials is required. To avoid accidental leakage or spillage, secondary containers, such as boxes, should be used, fitted with racks so that the specimen containers remain upright. The secondary containers may be of metal or plastic, should be autoclavable or resistant to the action of chemical disinfectants, and the seal should preferably have a gasket. They should be regularly decontaminated. The exterior surface of the secondary chamber should be decontaminated either chemically or in a fumigation chamber if the same plant, animal, host, or vector is present within the effective dissemination distance of the propagules/progenies of the experimental organism.

5. Storage

GMOs or infectious materials should be stored in a lockable facility so as to minimize handling in unconfined spaces. The GMO should be clearly identified and labeled to distinguish it from other stored materials, and preferably stored separately from related species to avoid contamination. Access to the storage facility should be limited to authorized individuals.

6. Personnel Safety

Personnel working in the containment facilities should adhere to good laboratory practices (GLPs) and avoid misuse of equipment that causes the majority of laboratory accidents, injuries and work-related hazards. Thus, a safety-conscious staff well informed about the recognition and control of laboratory hazards, personal protective equipment and clothing, is key to the prevention of laboratory-acquired infections, incidents and accidents. For this reason, continuous in-service training in safety measures is essential.

7. Records

The extent of record keeping required for research using GMO is commensurate with the level of biosafety. Records of experiments in progress must be kept for all biosafety levels. At BL2 and higher, additional records must be kept of all plants, animals and their associated organisms entering or leaving the containment facility. A record of the dates and times of personnel visits must be kept for BL4 facilities.

8. Termination and Disposal

To prevent the unintended survival of GMOs or infectious agents outside the contained environment, all experimental materials must be rendered biologically inactive (devitalized) before disposal. Devitalization can be achieved by burning, incineration, autoclaving or chemical treatment. Termination procedures for the safe disposal of soil, plant and animal material should be part of the experimental plan for a research project.

9. Training

Continuous in-service training in safety measures is essential for effective containment. An effective safety programme begins with the laboratory managers, who should ensure that safe laboratory practices and procedures are integrated into the basic training of employees. Training in safety measures should be an integral part of new employees' introduction to the laboratory.

10. Health and Medical Surveillance

The employing authority is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of such surveillance is to monitor for occupationally acquired diseases. Appropriate activities to achieve these objectives are to:

- a. Provide active or passive immunization where indicated
- b. Facilitate the early detection of laboratory-acquired infections
- c. Exclude highly susceptible individuals (such as pregnant women) from highly hazardous laboratory work
- d. Provide effective personal protective equipment and procedures.

11. Inspection

Inspections should be conducted on proposed new facilities, and regularly and also whenever new types of experimental materials are brought into an established facility. Inspectors from the Ministry responsible for Agriculture as well as any other agents authorized by UNCST should conduct this inspection for adequacy and compliance with the Terms and Conditions of authorization. A facility inspection checklist for containment of GMOs has been provided as Appendix 3. A copy of the inspection report should be submitted to the NBC Secretariat.

12. Contingency plans and emergency procedures

The Principal Investigator (PI) will establish a contingency plan for actions to be taken in case of emergency, or of unauthorized or accidental release of GM material or infectious agents (Appendix 4). A written contingency plan for dealing with laboratory and animal facility accidents is a necessity in any facility that works with or stores Risk Group 3 or 4 organisms.

1 Laboratory design and facilities

In designing a laboratory special attention should be paid to conditions that are known to pose safety problems such as unauthorized entry, overcrowding of equipment and experimental material, infestation with rodents and arthropods, formation of aerosols, and outside environmental contamination. Therefore the design features that require special attention are:

- a. Laboratory location and access
- b. Surface finishes and casework
- c. Ventilation and air conditioning
- d. Containment perimeter
- e. Laboratory services (i.e., water, drains, gas, electricity, and safety equipment)

The general requirements for the design features are given in Appendix 4.

2. Biological Safety Cabinets

Biological Safety Cabinets (BSCs) provide effective primary containment for work with human pathogens, when properly maintained and used in conjunction with good laboratory techniques. In BL2 laboratories, BSCs are used for procedures with the potential to produce infectious aerosols and for high concentrations or large volumes of infectious material. In BL3 and 4, all open vessel activities with infectious materials are conducted in a BSC. Every employee working in a BSC must be trained in its correct use and have a good understanding of the different types of cabinets and how they work. The three classes of BSC are described below:

Class I Cabinets (Figures 3)

These cabinets have non-recirculated airflow away from the operator that is discharged to the atmosphere after filtration through a High Efficiency Particulate Air (HEPA) filter. They provide good operator protection but do not protect the material within the cabinet (the product) from contamination.

Class II Cabinets (Figures 4-7)

Class II cabinets are designed for personnel, product and environmental protection. They are designed for work involving microorganisms in BL2, 3 and 4 laboratories. Class II is divided into Types A1, B1, B2 and B3 on the basis of construction type, airflow velocities and patterns, and exhaust systems. Air flow is drawn around the operator into the front grille of the cabinet, which provides personnel protection. In addition, the downward laminar flow of HEPA-filtered air provides product protection by minimizing the chance of cross-contamination along the work surface of the cabinet. Because cabinet air has passed through the exhaust HEPA filter, it is contaminant-free (environmental protection), and may be recirculated back into the laboratory (Type A BSC) or ducted out of the building (Type B BSC). The cabinet exhaust needs to be connected to the building exhaust.

Class III Cabinets (Figure 8)

Class III cabinets are totally enclosed and gas-tight with HEPA filtered supply and exhaust air. Work is performed with attached long-sleeved gloves. The cabinet is kept under negative pressure of at least 120 Pa (0.5 in. w.g.) and airflow is maintained by a dedicated exterior exhaust system. Class III cabinets protect the worker, product and environment. They are designed for work with level 4 pathogens and provide an alternative to the positive-pressure suit made for maximum containment laboratories. Cabinet lines consisting of several Class III cabinets (e.g. for centrifuges, animal cages, incubators, refrigerators) and transfer devices joined together are traditionally custom built. The exhaust air is double HEPA filtered or treated by HEPA filter and incineration. Removal of materials from the cabinet must be through a dunk tank, double door autoclave or air-lock pass-through for decontamination. Interlock or protocols must be used for the autoclave and pass-through doors to prevent both doors from being open at the same time.

Figure 3: Class I Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)

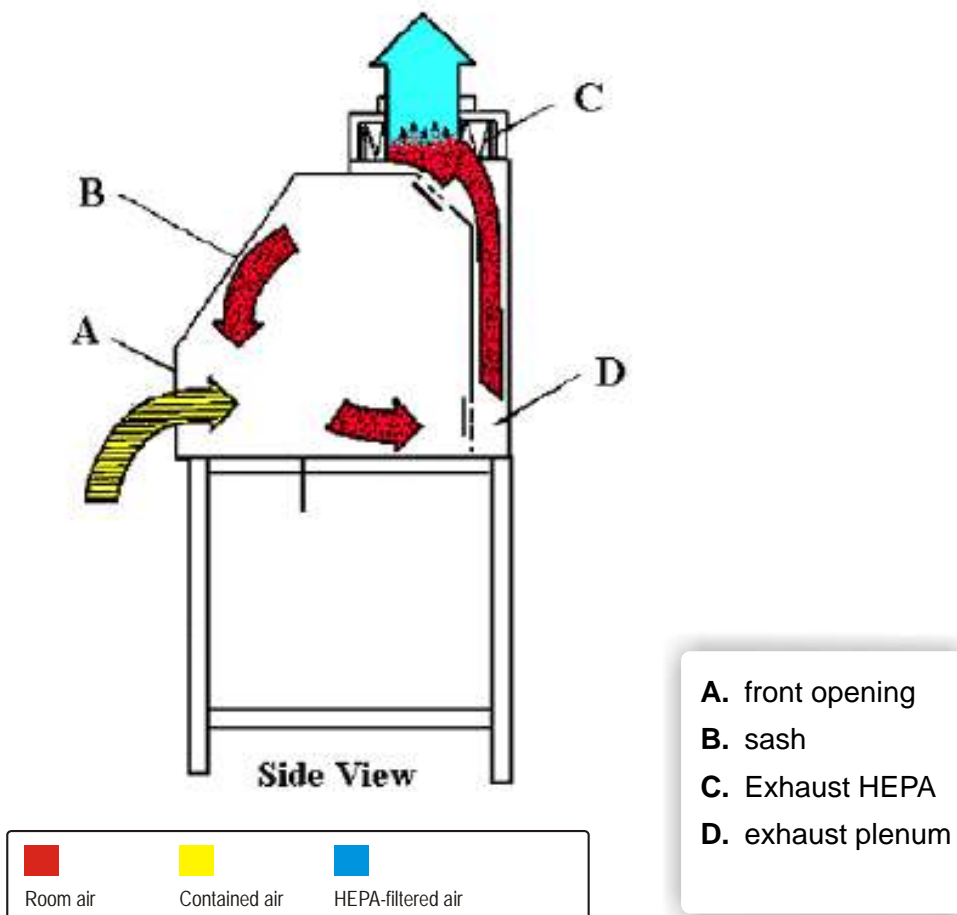
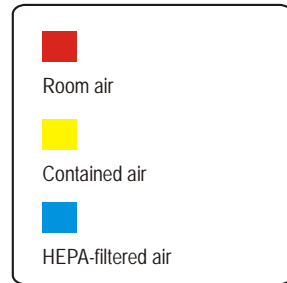
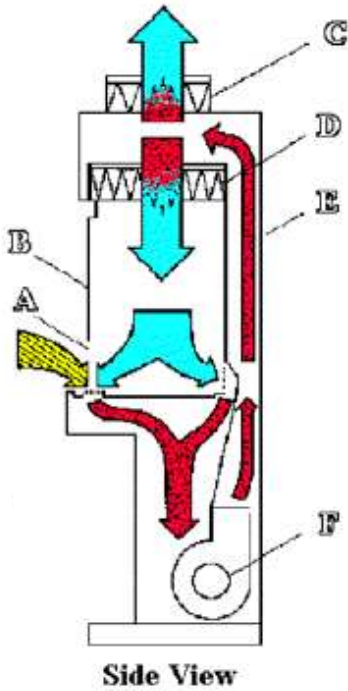
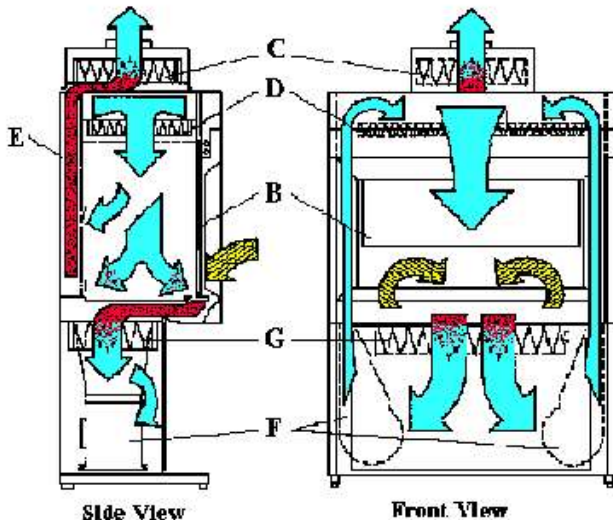


Figure 4: Class II A Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)



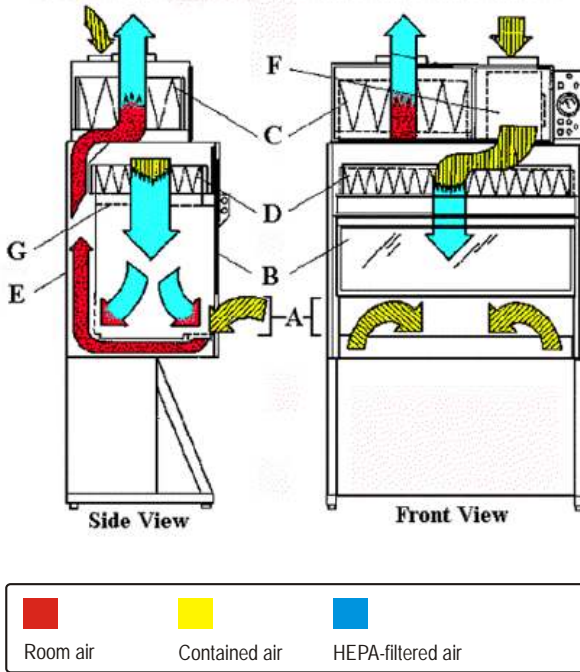
- A. front opening
- B. sash
- C. exhaust HEPA filter
- D. rear plenum
- E. supply HEPA filter
- F. Blower

Figure 5: Class II B1 Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)



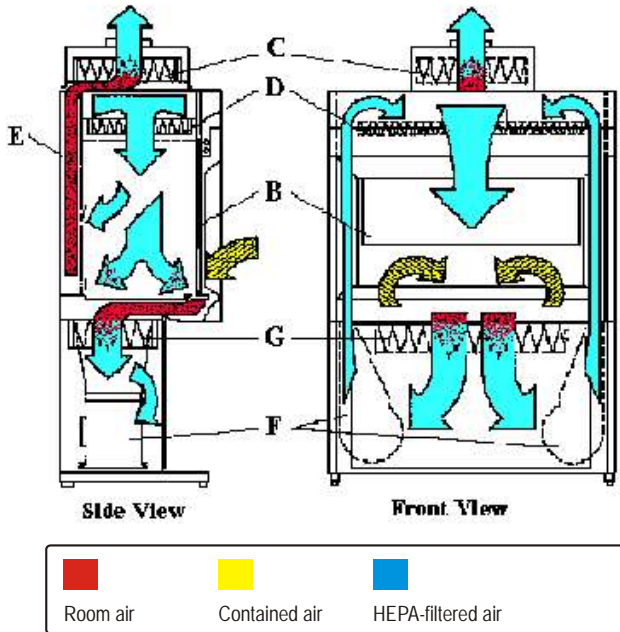
- A. front opening
- B. sash
- C. exhaust HEPA filter
- D. supply HEPA filter
- E. negative pressure exhaust plenum
- F. blower
- G. additional HEPA filter for air supply

Figure 6: Class II B2 Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)



- A.** front opening
- B.** sash
- C.** exhaust HEPA filter
- D.** supply HEPA filter
- E.** negative pressure exhaust plenum
- F.** supply blower
- G.** filter screen

Figure 5: Class II B1 Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)



- A.** front opening
- B.** sash
- C.** exhaust HEPA filter
- D.** supply HEPA filter
- E.** negative pressure exhaust plenum
- F.** blower
- G.** additional HEPA filter for air supply

Figure 6: Class II B2 Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)

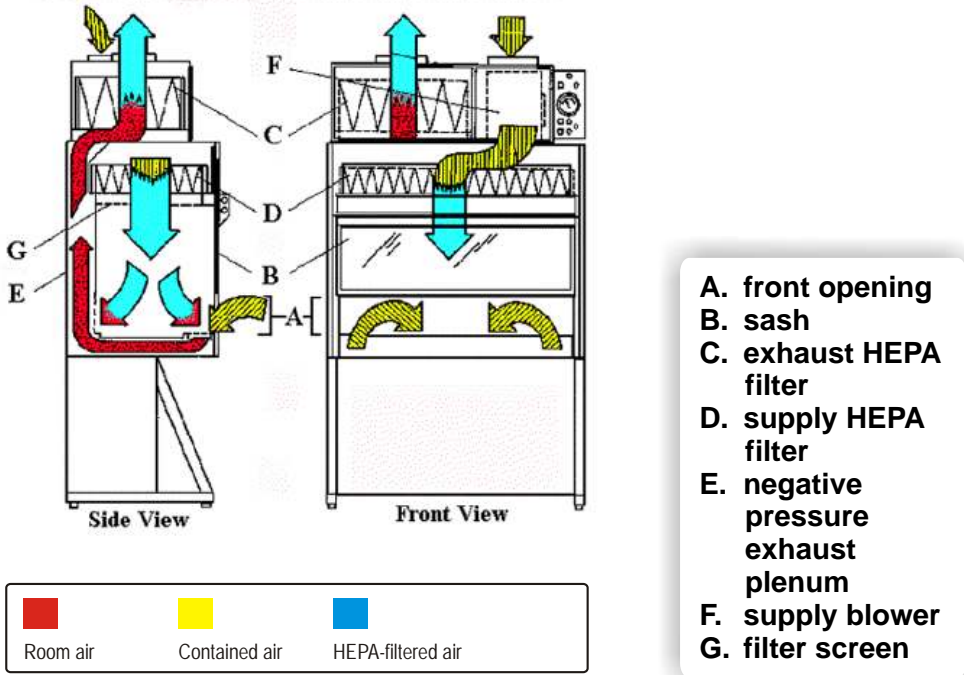


Figure 7: Class II B3 Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)

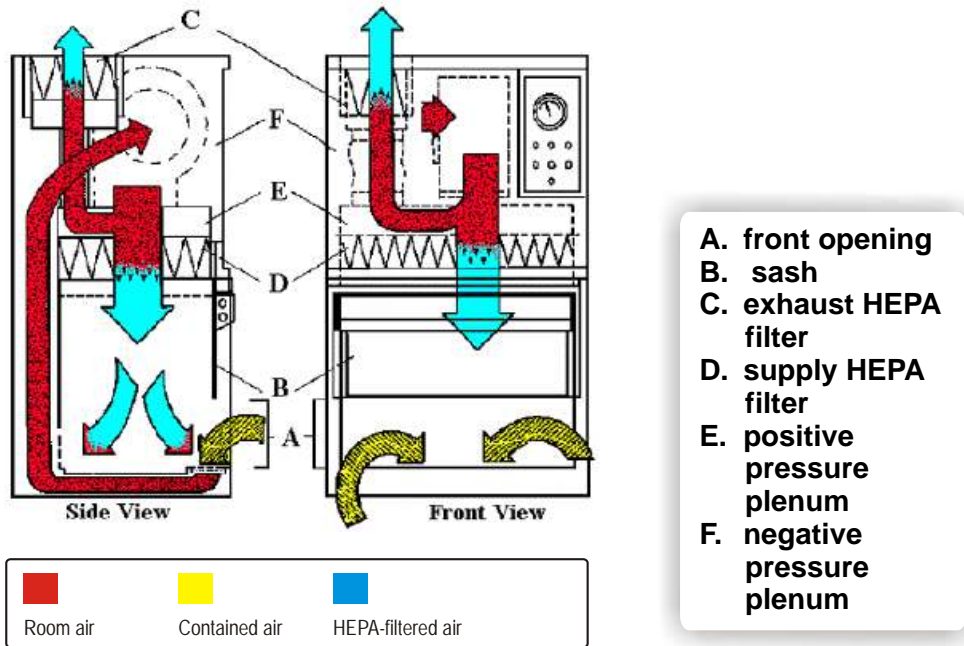
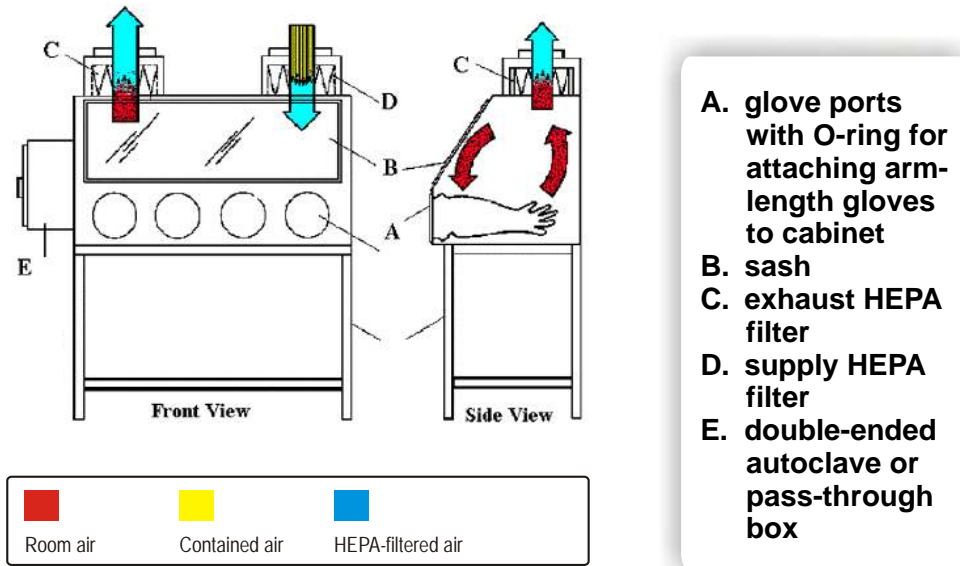


Figure 8: Class III Biological Safety Cabinet (USDHHS/PHS/CDC/NIH, 1995)



Selection of the proper class of BSC requires careful evaluation of the activities to be carried out (Table 5).

Table 5. Selection of Biological Safety Cabinets (BSCs), by type of protection needed

Type of Protection	BSC Selection
Personnel protection, microorganisms in Risk Group 1-3	Class I, II, III
Personnel protection, microorganisms in Risk Group 4, glove-box laboratory	Class III
Personnel protection, microorganisms in Risk Group 4, suit laboratory	Class I, II
Product protection	Class II, III only if laminar flow included

Horizontal Laminar Flow "Clean Bench"

Horizontal laminar flow clean air benches are not BSCs. They discharge HEPA-filtered air across the work surface and toward the user. These devices only provide product protection not for personnel. These benches should never be used as a substitute for a biological safety cabinet in research, biomedical or veterinary laboratories and/or applications.

Vertical Laminar Flow "Clean Bench"

Vertical laminar flow clean benches also are not BSCs. While these units generally have a sash, the air is usually discharged into the room under the sash, resulting in the same potential problems as the horizontal laminar flow clean benches.

3. Greenhouse design and facilities

The containment greenhouse and screen-house should be designed to meet the requirements for the Biosafety Level (Table 6).

Table 6. Enhanced features for containment green houses and screen houses

FEATURE	CONVENTIONAL	BL1	BL2	BL3	BL4
Structure	Framing may be aluminum, steel, wood, or pipe			Rigid, wind resistant frame preferred; internal walls, ceilings, and floors resistant to liquids and chemicals	Reinforced, rigid frame required; walls, floors, and ceilings form sealed internal shell, resistant to liquids and chemicals
Entry	Hinged or sliding entry doors		Locks on entry doors	Double set of self-closing, locking doors	Double set of self-closing, locking doors with air-lock; shower and changing rooms
Glazing	Standard greenhouse glass or plastic material			Laminated, strengthened, sealed	Double-paned, laminated, strengthened, sealed
Screening	If used, standard 30 mesh fly screen	Recommended	30-mesh or higher required	Not permitted	Not permitted
Ventilation	Roof or side vents, fans, cooling pads, fog system, or a combination of these			Separate negative pressure system; air supply fans with back-flow damper; exhaust air HEPA filtered	Air-conditioned and HEPA filtered, closely monitored negative pressure, no roof or side vent allowed
Benching	Any material; solid or porous bottoms			Seamless water and chemical resistant bench tops	Seamless water and chemical resistant bench tops
Floors	Gravel, soil, or concrete throughout	Impervious walkways recommended	Impervious material; collection of runoff water may be required	Impervious material; for microbes, runoff water collection and decontamination	Sealed floors as part of internal shell; runoff collection and decontamination
Drains	Discharge into groundwater or sanitary/storm sewer			Provision for collection and decontamination of runoff	Runoff collection required, sewer vents filtered
Other	Automatic control and utility systems meet basic operating requirements		Autoclave available	Autoclave within facility; hand washing with hands free on/off; filtered vacuum lines; disinfectant traps for liquid lines	Double-door autoclave; self-contained vacuum system; in-line filters and back-flow protection for all liquid/gas services

Source: Traynor *et al.*, 2001

Chapter 6

Commissioning, Certification and Recertification

For purposes of these Guidelines, "commissioning" is defined as the verification of the physical construction and performance of critical containment components, and is one part of the overall certification process. "Certification" is defined as the successful completion of commissioning and verification that the facility and operational protocols meet the requirements outlined in these Guidelines. "Recertification" is verification that the facility continues to comply with these Guidelines.

1. Commissioning

Commissioning is a process designed to ensure that the finished facility, equipment and systems will operate in accordance with the design intent and construction documents. Commissioning is recommended to be implemented early in the planning phase through to the construction and certification. To ensure that the physical requirements for the intended containment level and use of the facility have been met, each laboratory must undergo a detailed commissioning regime. This requires verification and documentation of critical containment components, equipment start-up, control system calibration, balancing and performance testing. Commissioning is a requirement for the certification of Biosafety levels 3 and 4 laboratories.

2. Certification

The critical containment components to be verified during initial certification are room integrity (smoke testing for leakages and pressure decay testing), air-handling systems, and laboratory equipments and services. Operational protocols must also be established before work with pathogens at the specified containment level can be carried out. Training of personnel is a critical aspect of this process and may involve initial work with pathogens normally requiring a lower containment level. Users must understand the containment systems and their operation in addition to scientific procedures. Detailed records of the certification process and test results must be maintained.

3. Recertification

Recertification of certain containment components should also be performed, the nature and frequency of which depend on a variety of factors. For example, verification of directional airflow, detection of any visual leaks in the room perimeter, recalibration of sensitive controllers and gauges, and monitoring of the efficacy of sterilization systems such as autoclaves can all be performed on a routine basis without disruption to the operation of the containment facility.

Selected References

Flanders Interuniversity Institute for Biotechnologies, 2002. Biosafety in the Laboratory, 2nd Edition, March 2002.

Health Canada, 2004. Laboratory Biosafety Guidelines, 3rd Edition, 2004.

Traynor Patricia L., Dann Adair, and Ruth Irwin, 2001. Greenhouse Research with Transgenic Plants and Microbes: A Practical Guide to Containment.

U.S. Department of Health and Human Services (USDHHS), and National Institutes of Health (NIH), 2002. NIH Guidelines for Research involving Recombinant DNA Molecules. April 2002.

U.S. Department of Health and Human Services (USDHHS), Public Health Service (PHS), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH), 1995. Selection, Installation and Use of Biological Safety Cabinets: Primary Containment for Biohazards. September 1995.

World Health Organization (WHO) 2004. Laboratory Biosafety Manual. 3rd Edition, 2004.

Appendices

Appendix 1: Notification of Intention to carry out Genetic Manipulation

To be completed by individual researchers and submitted to National Biosafety Committee (NBC) with comments of Institutional Biosafety Committee (IBC) for each specific experiment which, according to the revised guidelines, falls into containment Categories II, III, and IV in respect of a particular experiment involving genetic manipulation in a centre.

Submit the Original, Signed hard copy (with comments of the IBC) to the National Biosafety Committee (NBC) Secretariat, Uganda National Council for Science and Technology, Plot 10, Kampala Rd, 11 Floor Uganda House, P.O. Box 6884, Tel. 256-41-250499 Fax. 256-41-234579 Kampala, Uganda

You may use separate sheets of paper for detailing answers to the questions in this form. Such sheets must be properly attached to the form

Alternatively, the form could be filled electronically before printing it out. In such a case, enough spaces should be left for the IBC to fill.

Applications judged to be illegible, or vague would be returned to the Principal Investigator (Applicant)

1. Applicant:.....
Surname:.....Initials.....

2. Address :.....
Tel. No.....Fax.....

3. Title of project.....
.....

4. Summary.....
.....

5. Categorization of data
a) Source of nucleic acid.....
b) Specification of nucleic acid sequence.....
c) Vector host system.....

- d) Restriction map.....
- e) Manipulative procedures.....

6. Proposed containment category.....

.....

7. Comments by the Institutional Biosafety Committee (availability of facilities for and the nature of work proposed)

8. Plan of Investigation:.....

9. Physical containment:.....

10. Biological containment:.....

11. Subsequent use or distribution of recombinant DNA.....

12. Financial support:

- i) Research Activity.....
- ii) Containment facility: (If not existing).....

13. List of names and addresses staff involved with proposal:.....

14. Training- Steps taken to ensure that the staff members above are familiar with Biosafety guidelines and laboratory procedures involved with GM work

.....

.....

15. Arrangements made for health and environment monitoring

16. Institutional Biosafety Committee Membership:

17. Biological Safety/Medical Officer

Surname:.....Initials:.....

Address:.....

Training, Qualification, Experience

.....
.....
.....
.....

Tel. No..... E-mail.....Fax.....

Declaration:

18. The information provided in this form is to the best of my knowledge accurate. I have ensured that all persons nominated are fully aware of and are in agreement with the proposal.

(Signed).....Proposer.....Date.....

19. The proposal to carry out work in genetic manipulation has my authority and approval.

(Signed) Head of Department/Authorised official Date

.....

20. I agree to act as Biological Safety Officer/Medical Officer in connection with the work proposed in this submission.

(Signed) Biological Safety/Medical officer or deputy)

.....

Date.....

21. The proposal set out in this submission has been considered by a properly constituted Institutional Biosafety Committee of which I am the authorised representative and whose views on the proposal are accurately set out in Section 7 of this form.

(Signed).....

Authorised representative of Institutional Biosafety Committee

Title w.r.t the IBC.....

Date.....

Appendix 2.

Operational Practices for Containment Facilities (Adapted from Health Canada, 2004)

General practices (BL1-4)

The following general practices are required for all facilities handling genetically modified organisms and infectious substances.

- A documented safety manual must be available for all staff, and its requirements followed; it must be reviewed and updated regularly.
- Personnel must receive training on the potential risks associated with the work involved and the necessary precautions to prevent exposure and release of contained material. Training must be documented and signed by both the employee and supervisor.
- Eating, drinking, smoking, storing personal belongings are not permitted in any facility.
- Oral pipetting of infectious substance is prohibited in any laboratory.
- Access to containment facility is limited to authorized personnel.
- Doors to facility must not be left open and should open outward to allow ease of exit.
- Open wounds, cuts, scratches and grazes should be covered with waterproof dressings.
- Facilities are to be kept clean and tidy. Storage of materials that are not pertinent to the work should be minimized.
- Protective clothing, properly fastened, must be worn by all personnel, including visitors, trainees entering in the laboratory, and must be removed within the laboratory areas. Laboratory clothing must not be stored in contact with street clothing.
- Eye and face protection must be used where there is a known or potential risk of exposure to splashes or flying objects.
- Gloves (e.g., latex, vinyl, co-polymer) must be worn for all procedures that might involve direct skin contact with infectious material and should be removed when leaving the laboratory and decontaminated.
- Hands must be washed after gloves have been removed and at any time after handling materials known or suspected to be contaminated.
- If a known or suspected exposure occurs, contaminated clothing must be decontaminated before laundering.
- The use of needles, syringes and other sharp objects should be strictly limited to avoid auto-inoculation and the generation of aerosols during use and disposal.
- Work surfaces must be cleaned and decontaminated with a suitable disinfectant at the end of the day and after any spill of potentially infectious material; work surfaces that have become permeable must be replaced or repaired.
- Contaminated materials and equipment leaving the laboratory for servicing or disposal must be appropriately decontaminated and tagged out as such.
- Efficacy monitoring of autoclaves used for decontamination with biological indicators must be done regularly and the records of these results and cycle logs (i.e., time, temperature and pressure) must also be kept on file.
- All contaminated materials must be decontaminated before disposal or reuse. Disinfectants effective against the agents in use must be available at all times within the areas where the infectious material is handled or stored.

- ? Leak-proof containers are to be used for the transport of infectious materials within facilities.
- ? Spills, accidents or exposures to infectious materials and losses of containment must be reported immediately to the facility manager; written records of such incidents must be maintained, and the results of incident investigations should be used for continuing education.
- ? An effective rodent and insect control program must be maintained.

Biosafety Level 2

In addition to the general practices required for all containment facilities, the following describe the minimum operational practices required for Biosafety level 2.

- ? BSCs must be used for procedures that may produce infectious aerosols and that involve high concentrations or large volumes of infectious material. Laboratory managers and PI, in consultation with the Biological Safety Officer/Institutional Biosafety Committee, should perform a risk assessment to determine which procedures and what concentrations and volumes necessitate the use of a BSC.
- ? Appropriate signage indicating the biosafety level and biohazard sign must be posted outside each facility.
- ? Entry must be restricted to facility staff, maintenance staff and authorized visitors.
- ? All people working in the containment area must be trained in and follow the operational protocols for the project in process. Trainees must be accompanied by a trained staff member.
- ? Emergency procedures for spill clean-up, BSC failure, fire, animal escape and other emergencies must be written, easily accessible and followed. A record must be made of other people entering the facility during an emergency.

Biosafety Level 3

In addition to the general practices and those minimum requirements for Biosafety level 2, the following describe the minimum operational practices required at Biosafety level 3.

- ? There must be a program for the management of biological safety issues in place with appropriate authority to oversee safety and containment practices.
- ? Everyone entering the containment facility must have completed a training course in procedures specific to the Biosafety level.
- ? Employees working in the containment area must have knowledge of the physical operation and design of the facility (e.g., air pressure gradients between zones, directional airflow patterns, alarm signals for air pressure failure, containment perimeter).
- ? A protocol specific to the operation of the facility must be developed and read by personnel who must certify in writing that they have understood the material in the protocol.
- ? Personnel must have demonstrated proficiency in microbiological practices and techniques.
- ? Smoke testing should be done periodically by facility staff to verify correct airflow; a containment check must be performed before entering the containment laboratory (e.g., verify correct reading on the pressure monitoring device).
- ? People entering a containment facility must be well prepared and bring all materials they will need with them; if something has been forgotten, established traffic patterns must still be adhered to (i.e., do not go back to get it; either phone for someone to bring it or exit using proper protocols).
- ? Routine cleaning must be done by personnel using the containment facility or by specific personnel dedicated and trained for this task.
- ? The containment facility must be kept locked.
- ? Genetically modified organisms and infectious agents should be stored inside the containment facility; material stored outside of the zone must be kept locked, in leak-proof containers; emergency response procedures are to take into account the existence of such material outside of the containment facility.

- ? Leak-proof containers are to be used for the transport of infectious materials within facilities.
- ? Spills, accidents or exposures to infectious materials and losses of containment must be reported immediately to the facility manager; written records of such incidents must be maintained, and the results of incident investigations should be used for continuing education.
- ? An effective rodent and insect control program must be maintained.

Biosafety Level 2

In addition to the general practices required for all containment facilities, the following describe the minimum operational practices required for Biosafety level 2.

- ? BSCs must be used for procedures that may produce infectious aerosols and that involve high concentrations or large volumes of infectious material. Laboratory managers and PI, in consultation with the Biological Safety Officer/Institutional Biosafety Committee, should perform a risk assessment to determine which procedures and what concentrations and volumes necessitate the use of a BSC.
- ? Appropriate signage indicating the biosafety level and biohazard sign must be posted outside each facility.
- ? Entry must be restricted to facility staff, maintenance staff and authorized visitors.
- ? All people working in the containment area must be trained in and follow the operational protocols for the project in process. Trainees must be accompanied by a trained staff member.
- ? Emergency procedures for spill clean-up, BSC failure, fire, animal escape and other emergencies must be written, easily accessible and followed. A record must be made of other people entering the facility during an emergency.

Biosafety Level 3

In addition to the general practices and those minimum requirements for Biosafety level 2, the following describe the minimum operational practices required at Biosafety level 3.

- ? There must be a program for the management of biological safety issues in place with appropriate authority to oversee safety and containment practices.
- ? Everyone entering the containment facility must have completed a training course in procedures specific to the Biosafety level.
- ? Employees working in the containment area must have knowledge of the physical operation and design of the facility (e.g., air pressure gradients between zones, directional airflow patterns, alarm signals for air pressure failure, containment perimeter).
- ? A protocol specific to the operation of the facility must be developed and read by personnel who must certify in writing that they have understood the material in the protocol.
- ? Personnel must have demonstrated proficiency in microbiological practices and techniques.
- ? Smoke testing should be done periodically by facility staff to verify correct airflow; a containment check must be performed before entering the containment laboratory (e.g., verify correct reading on the pressure monitoring device).
- ? People entering a containment facility must be well prepared and bring all materials they will need with them; if something has been forgotten, established traffic patterns must still be adhered to (i.e., do not go back to get it; either phone for someone to bring it or exit using proper protocols).
- ? Routine cleaning must be done by personnel using the containment facility or by specific personnel dedicated and trained for this task.
- ? The containment facility must be kept locked.
- ? Genetically modified organisms and infectious agents should be stored inside the containment facility; material stored outside of the zone must be kept locked, in leak-proof containers; emergency response procedures are to take into account the existence of such material outside of the containment facility.

- ? Leak-proof containers are to be used for the transport of infectious materials within facilities.
- ? Spills, accidents or exposures to infectious materials and losses of containment must be reported immediately to the facility manager; written records of such incidents must be maintained, and the results of incident investigations should be used for continuing education.
- ? An effective rodent and insect control program must be maintained.

Biosafety Level 2

In addition to the general practices required for all containment facilities, the following describe the minimum operational practices required for Biosafety level 2.

- ? BSCs must be used for procedures that may produce infectious aerosols and that involve high concentrations or large volumes of infectious material. Laboratory managers and PI, in consultation with the Biological Safety Officer/Institutional Biosafety Committee, should perform a risk assessment to determine which procedures and what concentrations and volumes necessitate the use of a BSC.
- ? Appropriate signage indicating the biosafety level and biohazard sign must be posted outside each facility.
- ? Entry must be restricted to facility staff, maintenance staff and authorized visitors.
- ? All people working in the containment area must be trained in and follow the operational protocols for the project in process. Trainees must be accompanied by a trained staff member.
- ? Emergency procedures for spill clean-up, BSC failure, fire, animal escape and other emergencies must be written, easily accessible and followed. A record must be made of other people entering the facility during an emergency.

Biosafety Level 3

In addition to the general practices and those minimum requirements for Biosafety level 2, the following describe the minimum operational practices required at Biosafety level 3.

- ? There must be a program for the management of biological safety issues in place with appropriate authority to oversee safety and containment practices.
- ? Everyone entering the containment facility must have completed a training course in procedures

Appendix 3.

Facility Inspection Checklist for Containment of GMOs

Address of Facility

Applicant (Responsible Person)

Name _____

Address _____

Location of all facilities covered by this inspection

Building Name

Room/Laboratory

Growth Chamber Identification

Greenhouse Number or other Identification

Research qualifications and general background

1. Does this facility operate under the National Containment guidelines? Yes ___ No ___
2. Is there a written policy regarding handling of rDNA at this establishment? Yes ___ No ___
3. Who is the chairperson of the local Institutional Biosafety Committee (IBC)?
Name and Title _____
4. Who is the scientist who will conduct the research?
Name and Title _____
5. Is the scientist who is conducting the research the applicant? Yes ___ No ___
6. What other scientists and technicians will be working on the research?
Describe, in a general way, their experience and qualifications.
7. Do researchers and laboratory technicians practice to the National Containment guidelines?
Yes ___ No ___

Physical design and security

8. Provide a short description of how the regulated article is physically marked and identified in the laboratory, growth chamber, and greenhouse. Provide floor plan and/or map of facilities if possible.
9. Is the general area secure from public access? Yes___ No___
If not, please elaborate.
10. a. Is the general area secure from unauthorized personnel? Yes___ No___
If not, please elaborate.
- b. Can individual laboratories be locked? Yes___ No___
- c. Is there at least one sign posted on the facility door stating that a regulated genetically engineered organism is present? Yes___ No___
If not, when will a sign be installed? Date _____
11. Who is allowed in the research areas?
Cleaning Personnel Yes___ No___ Trades Persons Yes___ No___
Other Yes__ No___
12. How distant from each other are the germination laboratories, growth chambers, and greenhouses?
Be specific.
13. What kind of records, logs, or inventory are maintained regarding receipt, increase, and destruction of regulated articles?

Handling of materialgermination

14. A. Is there a cabinet to store seeds, plant material, tissue cultures, etc.? Yes___ No___
- B. If yes, does it have a lock? Yes___ No___
- C. Is the storage container identified with a sign stating it contains a genetically engineered organism?
Yes___ No___
- D. If not, when will a sign be installed? Date _____

15. Where will seeds, tissue cultures, plant material, etc. be grown or germinated?

16. What medium will be used for seed germination? (e.g., germination paper, perlite, sand)

17. Is there any danger of seeds, tissue cultures, plant material, etc. being lost during this germination process, or of ungerminated seed being transferred into subsequent research stages? Yes____
No____

18. Are there any cracks or irregular surfaces in the germination laboratory that could trap seeds?
Yes____ No____
If Yes, describe size and location of cracks.

19. Are there water drains in the laboratory? Yes____ No____

20. Are the drains screened? Yes____ No____
If so, what is the size of the screen?

21. Does the drain system enter into a special waste trap? Yes____ No____

22. How will the germinated seed be moved to the growth chamber?

23. How will petri dishes, tissue cultures, spores, plant materials, etc. be moved from the laminar flow hood, to the incubator, to the growth chamber?

24. How will the regulated articles be kept separate from other organisms?

Handling of materialgrowth chamber

25. Does growth chamber have access by authorized personnel only? Yes____ No____
26. Describe the growth chamber. lab top____ walk in____ built on site____ other ____.
27. Will the material be grown with any other plant materials in the same chamber?
Yes____ No____
If yes, name the types of plants.

28. How will genetically engineered plants and/or containers be physically marked?
29. Does the growth chamber have water drains? Yes____ No____
If so, can they be screened? Yes____ No____
30. Does the drain system enter into a special waste trap? Yes____ No____
31. Where is the autoclave or incinerator in relation to the growth chamber?
32. Can the growth chamber be locked and separated from other growth chamber(s)? Yes____ No____
33. How will the material be transferred to the greenhouse?
34. How will the regulated articles be kept separate from other organisms?

Handling of materialgreenhouse

35. What is the name of the greenhouse manager?
36. Is the greenhouse accessed by authorized personnel only? Yes____ No____
37. a. Does the greenhouse have a double door entry system? Yes____ No____
b. Is the greenhouse entry through a "head-house"? Yes____ No____
38. a. Do the greenhouse doors have locks? Yes____ No____
b. Is there a rear exit door? Yes____ No____
39. What type of greenhouse? Glass____ Lexan____ Plastic____ Poly____ Screen____ Other____
If screen, what size mesh? _____ If Poly, what thickness? Name and

40. What are the approximate outside dimensions of the greenhouse(s)?
41. a. Do the roof vents open? Yes____ No____
b. If the roof vent opens, is it screened? Yes____ No____ What size is the screen mesh?

42. What kind of floor does the greenhouse have? Concrete____ Gravel____ Packed Dirt____
Other____ (Explain)_____
43. Does the greenhouse have water drains? Yes____ No____
Do they enter into a special waste trap? Yes____ No____

- 44. a. Does the greenhouse have black light traps for vectors? Yes____ No____
- b. Does the greenhouse have "Sticky Board" traps for vectors? Yes____ No____
- c. Does the greenhouse have other kinds of vector traps? Describe.
- 45. How will the plants be grown in the greenhouse? On Benches____ In Flats____ In Pots____,
Other (Describe)_____
- 46. Will there be physical markers on each plant or container indicating that the plants are genetically engineered? Yes____ No____
- 47. Where is the autoclave or incinerator in relation to where the plants will be grown?
- 48. Are there any openings in the greenhouse through which animals and pollinating insects could enter?
Yes____ No____
- 49. How will the regulated articles be kept separate from other organisms?

General considerations

What kinds of "spill response" action plan/equipment is available for items spilled in transit between labs, chambers, and greenhouses? Items should be carried in containers so spills should not occur.

Are any similar plants growing in the area, either on the facility grounds or outside of the facility grounds?

What other factors are present which may influence the handling of seed or plants and may have an effect on containment or risk?

Inspect for other specific conditions as stipulated on the permit.

Name of Inspection Organization_____

Name of Inspecting Officer_____

Signature_____

Appendix 4.

Contingency Plan for Emergency Response

A contingency plan is drawn to provide a procedure to be followed if the Principal Investigators and/or their staff in case they are faced with an emergency such as unauthorized or accidental release of GM material or infectious agents.

Procedure:

Principal Investigators shall include the following when developing Emergency Response Procedures for their Containment Facilities:

1. Any staff, if they are unable to attend due to an emergency situation for a day or several days, shall inform the Principal Investigator and/or facility manager.
2. Principal Investigator and/or facility manager shall ensure that the facility access is limited to only authorized persons.
3. Principal Investigator and/or facility manager shall ensure that the facility is secure with respect to ongoing research activities.
4. In the event of an accidental release of contained material, the incident should be stabilized.
 - i. The PI and Biological Safety Officer (BSO) should be immediately notified of the situation.
 - ii. The BSO should ensure as much of the experimental material is contained and secured as possible.
 - iii. The incident should be documented as follows:
 - The date, time and place of the incident;
 - A description of the incident;
 - The name of the authority contacted;
 - How the emergency was handled to minimize risk.
 - iv. If the emergency situation is such that neither the Principal Investigator nor the BSO can address it then the national emergency services shall be notified by the Principal Investigator and/or BSO making specific reference to the potential hazards.
 - v. After corrective action is taken to address an accidental release, the PI should undertake a timely review of the situation to identify the cause(s) and institute changes in management practices or training of personnel to ensure that the situation is not repeated.
 - vi. No new GM material or infectious agents will be accepted, in the facility until the emergency situation has been rectified.

NB: Specific contingency plans will be established based on the type of Research

Appendix 5

General requirements for laboratory design

Laboratory Location and Access

Criteria	Biosafety levels			
	BL1	BL2	BL3	BL4
1 Separated from public areas by doors	■	■	■	■
2 Access limited to authorized personnel		■	■	■
3 Laboratory room doors to have appropriate signage which should include but not limited to biohazard signs, containment level, contact and emergency information, entry requirements		■	■	■
4 Size of doors should allow passage of all anticipated equipment	■	■	■	■
5 Doors to the containment laboratory lockable		■	■	■
6 Doors should open either both ways or to the outside of the laboratory	■	■	■	■
7 Doors should have view glass panels	■	■	■	■
8 Doors to provide restricted access by installation of a suitable controlled access system			■	■
9 Electronic locking systems to be backed up with a physical key-lock system			□	■
10 Office areas to be located outside of containment laboratory		□	■	■
11 Entry to laboratory to be provided via an anteroom (antechamber)			■	■
12 Entry to laboratory to be provided with clothing change areas separating personal and laboratory clothing (i.e., "clean" change area separated from "dirty" change area)				
13 Exit from laboratory to be provided with a walk through shower on the containment barrier - between "dirty" and "clean" change anterooms.			■	
14 Entry to laboratory to be provided via anteroom with airtight doors; for laboratories using only a Class III BSC, airtight doors are not required.				■
15 Entry to laboratory to be provided with a suit change area, a chemical shower on the containment barrier and water shower on the exit; for laboratories using only a Class III BSC, suit change area and chemical shower are not required.			■	■
16 Containment laboratories to be located in close proximity to supporting mechanical services to limit the amount of potentially contaminated services.			□	■
17 A laboratory support area to be provided adjacent to the containment facility for all supporting laboratory manipulations.			□	□

Mandatory requirement ■ Recommended requirement □

Surface Finishes and Casework

Criteria	Biosafety levels			
	BL1	BL2	BL3	BL4
1 Doors, frames, casework and bench tops to be non -absorptive (i.e., the use of organic materials should be avoided).		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2 Working surfaces of bench tops to be non-absorptive.		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3 Surfaces to be scratch, stain, moisture, chemical, heat and impact resistant in accordance with laboratory function.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4 Surfaces to be continuous and compatible with adjacent and overlapping materials (i.e., to maintain adhesion and a continuous perimeter); wall and floor welded seams are acceptable in level 3 laboratories. Continuity of seal to be maintained between the floor and wall (a continuous cove floor finish up the wall is recommended).		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5 Interior surfaces to minimize movement of gases and liquid through perimeter membrane (e.g. on walls, floors and ceilings).			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6 Interior coatings to be gas and chemical resistant in accordance with laboratory function (e.g., will withstand chemical disinfection, fumigation).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7 Interior coatings to be cleanable			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
8 Structural stability to withstand 1.25 times maximum design pressure under supply and exhaust fan failure conditions (i.e., no wall distortion or damage)				<input checked="" type="checkbox"/>
9 Bench tops to have no open seams.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
10 Benches, doors, drawers, door handles, etc. to have rounded rims and corners.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11 Reagent shelving to be equipped with lip edges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12 Drawers to be equipped with catches, i.e., to prevent the drawer from being pulled out of the cabinet.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13 Drawers to be of one piece construction				<input type="checkbox"/>
14 Cabinet doors not to be self-closing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Mandatory requirement

Recommended requirement

Ventilation and Air Conditioning

Criteria	Biosafety levels			
	BL1	BL2	BL3	BL4
1 100% outside air to be supplied		☐	■	■
2 Directional inward airflow provided such that air will always flow towards areas of higher containment (e.g., ± 25 Pa differential)			■	■
3 Visual pressure differential monitoring devices to be provided at entry to containment laboratory			■	■
4 Room pressure differential monitoring lines penetrating the containment barrier to be provided with filters of efficiency equal to that of HEPA filtration				■
5 Alarm (visual or audible) to be provided in the laboratory and outside laboratory area (i.e., to warn others and maintenance personnel) to signal air handling systems failure			■	■
6 Where determined necessary by a local risk assessment, supply air duct to be provided with backdraft protection (i.e., HEPA filter; bubble tight backdraft damper)			■	
7 Supply air to be HEPA filtered (to conform to the requirements of the National Bureau of Standards)		☐	■	■
8 Supply air system to be independent of other laboratory areas. BL3 supply can be combined with areas of lower containment when provided with backdraft protection (i.e., HEPA filter, bubble tight backdraft damper) downstream from the connection			■	■
9 Supply air system to be interlocked (i.e., fans, dampers, electrical) with exhaust air system, to prevent sustained laboratory positive pressurization			■	■
10 Exhaust air to be HEPA filtered			■	■
11 Exhaust air to be passed through two stages of HEPA filtration			■	■
12 Where HEPA filters are used for backdraft protection in accordance with local risk assessment, supply HEPA filter housings to be designed to withstand structural change at applied pressure of 2500 Pa [10 in. w.g.].			■	■
13 Exhaust HEPA filter housings to be designed to withstand structural change at applied pressure of 2500 Pa [10 in. w.g.] and to be provided with a method of isolation and decontamination.			■	■
14 Exhaust air system to be independent of other laboratory areas. BL3 exhaust can be combined with areas of lower containment when provided with a HEPA filter upstream from the connection.				
15 Supply and exhaust systems located outside of containment to be accessible for repairs, maintenance, cleaning and inspection.			☐	■
16 Supply air ductwork that is outside the containment perimeter (e.g., between containment perimeter and HEPA filter or bubble tight backdraft damper) to be sealed airtight in accordance with National Standards Competent Authority (NSCA)			■	■
17 Where backdraft protection is required in accordance with local risk assessment, supply air ductwork that is outside the containment perimeter (e.g., between containment perimeter and HEPA filter or bubble tight backdraft damper) to be sealed airtight in accordance with National Standards Competent Authority (NSCA)			■	■
18 Where backdraft protection is required in accordance with local risk assessment, supply air ductwork that is outside the containment perimeter (e.g., between containment perimeter and HEPA filter or bubble tight backdraft damper) to be sealed airtight in accordance with NSCA			■	■
19 Bubble tight backdraft dampers and HEPA filters to be located in close proximity to the containment perimeter.			■	■

Mandatory requirement ■

Recommended requirement ☐

Containment Perimeter

Criteria	Biosafety levels			
	BL1	BL2	BL3	BL4
1 Autoclave or other acceptable means of waste treatment/disposal to be provided	■	□		
2 Double-door barrier autoclave with bioseal to be located on containment barrier; body of autoclave to be preferably located outside of containment for ease of maintenance			■	■
3 Barrier autoclave to be equipped with interlocking doors, or visual or audible alarms to prevent both doors from opening at the same time			■	
4 Barrier autoclave to be equipped with interlocking doors, and visual or audible alarms to prevent both doors from opening at the same time				■
5 For materials that cannot be autoclaved (e.g., heat sensitive equipment, samples, film) other proven technologies for waste treatment (e.g., incineration, chemical, or gas) to be provided at containment barrier.	□	□	■	■
6 All penetrations to be sealed with non shrinking sealant at containment barrier			■	■
7 All conduit and wiring to be sealed with non-shrinking sealant at the containment barrier			■	■
8 Windows, if they can be opened, to be protected by fly screens	■	■		
9 Windows positioned on containment barrier to be sealed in place; window glazing material to provide required level of security.			■	■
10 Observation windows to be installed on containment barrier			□	□

Mandatory requirement ■ Recommended requirement □

Laboratory Services (i.e., water, drains, gas, electricity, and safety equipment)

Criteria	Biosafety levels			
	BL1	BL2	BL3	BL4
1 Hooks to be provided for laboratory coats at laboratory exit; street and laboratory clothing areas to be separated	■	■		
2 Hand washing sinks to be located near the point of exit from the laboratory or in anteroom. Not applicable to BL4 suit laboratories.	■	■	■	■
3 Hand washing sinks to be provided with "hands-free" capability		□	■	■
4 BSCs and other primary containment devices to be provided		□	■	■
5 Emergency eyewash facilities to be provided in accordance with applicable regulations		□		
6 Emergency shower equipment to be provided in accordance with applicable regulations	□	■	■	
7 Domestic water branch piping serving laboratory area(s) to be provided with backflow prevention, in accordance with NSCA and isolation valve, to be located in close proximity to the containment barrier			■	■
8 Drain lines and associated piping (including autoclave condensate) to be separated from lower containment laboratory areas and to go directly to main building sanitary sewer at point of exit from building (downstream of all other connections)			■	
9 Drain lines and associated piping (including autoclave condensate) to be separated from areas of lower containment and to be connected to an effluent sterilization system				■
10 Drains connected to effluent sterilization to be sloped towards sterilization system to ensure gravity flow; consideration should be given to the installation of valves to isolate sections of piping for <i>in situ</i> decontamination; the effluent sterilization system (e.g., piping, valves, tank) to be heat and chemical resistant consistent with application.				■
11 Autoclave condensate drain to have a closed connection. For BL3, open connection is allowable if located within containment barrier.			■	■
12 Drainage traps to be provided to required deep seal depth in consideration of air pressure differentials			■	■
13 Floor drains not to be provided, except when essential (e.g., body shower and animal rooms).			□	■
14 Plumbing vent lines (including effluent sterilization system) to be provided with filter of efficiency equivalent to that of HEPA and provided with a means of isolation and decontamination				■
15 Plumbing vent lines to be independent of lower containment plumbing vent lines, or combined with lines from lower containment when provided with a filter of efficiency equivalent to that of HEPA upstream from the connection			■	
16 Compressed gas cylinder(s) to be located outside the laboratory		■	■	■
17 Laboratory supply gas piping (e.g., carbon dioxide, compressed air) to be provided with backflow prevention.				
18 Portable vacuum pump to be provided in the laboratory Internal contamination of vacuum pump to be minimized (e.g., HEPA filtration of vacuum line, use of disinfectant traps).			■	■
19 Compressed breathing air to be provided to positive-pressure personal protective equipment (i.e., for connection to the air hose of suits), equipped with breathing air compressors and back-up cylinders (sufficient for 30 minutes per person); air hose connections to be provided in all areas where suits are worn, including chemical shower and suit change room				■
20 Emergency lighting to be provided			■	■
21 Life safety systems, lighting, VAC systems, BSCs, security systems and other essential equipment to be supported with emergency back-up power.			■	■
22 Circuit breakers to be located outside biocontainment area.			□	□
23 Fluorescent light ballasts and starters to be located outside containment area.			■	□
24 Laboratory to be equipped with a communication system between containment			■	□

Mandatory requirement ■

Recommended requirement □

Appendix 6.

Classification of Pathogens on the Basis of Hazard

Human Etiologic Agents (USDHHS/NIH, 2002).

Biological agents known to infect humans as well as selected animal agents that may pose theoretical risks if inoculated into humans are given below. Included are lists of representative genera and species known to be pathogenic; mutated, recombined, and non-pathogenic species and strains are not considered. Non-infectious life cycle stages of parasites are excluded.

This is the current state of knowledge and should be considered a resource document. Included are the more commonly encountered agents and is not meant to be all-inclusive. Information on agent risk assessment may be found in the *Agent Summary Statements* of the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* (4th Edition, 1999), *Classification of Etiologic Agents on the Basis of Hazard* (4th Edition, 1974), *Control of Communicable Diseases Manual* (17th Edition, 2000) and *World Health Organization Laboratory Biosafety Manual* (2nd Edition, 1993). Further guidance on agents not listed in this appendix may be obtained through: Centers for Disease Control and Prevention, Biosafety Branch, Atlanta, Georgia 30333.

1. Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis* (*Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems, Exceptions); adeno-associated virus (AAV) types 1 through 4; and recombinant AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of *Escherichia coli* is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (*i.e.*, lacks the O antigen); and (2) does not carry any active virulence factor (*e.g.*, toxins) or colonization factors and does not carry any genes encoding these factors.

Those agents not listed in Risk Groups (RGs) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

2. Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available. They include:

RG2 Bacterial Agents Including Chlamydia

- *Acinetobacter baumannii* (formerly *Acinetobacter calcoaceticus*)
- *Actinobacillus*
- *Actinomyces pyogenes* (formerly *Corynebacterium pyogenes*)
- *Aeromonas hydrophila*
- *Amycolata autotrophica*
- *Archanobacterium haemolyticum* (formerly *Corynebacterium haemolyticum*)
- *Arizona hinshawii* - all serotypes
- *Bacillus anthracis*
- *Bartonella henselae*, *B. quintana*, *B. vinsonii*
- *Bordetella* including *B. pertussis*
- *Borrelia recurrentis*, *B. burgdorferi*
- *Burkholderia* (formerly *Pseudomonas* species) except those listed in Appendix B-III-A (RG3))

- ? *Campylobacter coli*, *C. fetus*, *C. jejuni*
- ? *Chlamydia psittaci*, *C. trachomatis*, *C. pneumoniae*
- ? *Clostridium botulinum*, *Cl. chauvoei*, *Cl. haemolyticum*, *Cl. histolyticum*, *Cl. novyi*, *Cl. septicum*, *Cl. tetani*
- ? *Corynebacterium diphtheriae*, *C. pseudotuberculosis*, *C. renale*
- ? *Dermatophilus congolensis*
- ? *Edwardsiella tarda*
- ? *Erysipelothrix rhusiopathiae*
- ? *Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7
- ? *Haemophilus ducreyi*, *H. influenzae*
- ? *Helicobacter pylori*
- ? *Klebsiella* - all species except *K. oxytoca* (RG1)
- ? *Legionella* including *L. pneumophila*
- ? *Leptospira interrogans* - all serotypes
- ? *Listeria*
- ? *Moraxella*
- ? *Mycobacterium* (except those listed in RG3) including *M. avium* complex, *M. asiaticum*, *M. bovis* BCG vaccine strain, *M. chelonae*, *M. fortuitum*, *M. kansasii*, *M. leprae*, *M. malmoense*, *M. marinum*, *M. paratuberculosis*, *M. scrofulaceum*, *M. simiae*, *M. szulgai*, *M. ulcerans*, *M. xenopi*
- ? *Mycoplasma*, except *M. mycoides* and *M. agalactiae* which are restricted animal pathogens
- ? *Neisseria gonorrhoeae*, *N. meningitidis*
- ? *Nocardia asteroides*, *N. brasiliensis*, *N. otitidiscaviarum*, *N. transvalensis*
- ? *Rhodococcus equi*
- ? *Salmonella* including *S. arizonae*, *S. choleraesuis*, *S. enteritidis*, *S. gallinarum-pullorum*, *S. meleagridis*, *S. paratyphi*, A, B, C, *S. typhi*, *S. typhimurium*
- ? *Shigella* including *S. boydii*, *S. dysenteriae*, type 1, *S. flexneri*, *S. sonnei*
- ? *Sphaerophorus necrophorus*
- ? *Staphylococcus aureus*
- ? *Streptobacillus moniliformis*
- ? *Streptococcus* including *S. pneumoniae*, *S. pyogenes*
- ? *Treponema pallidum*, *T. carateum*
- ? *Vibrio cholerae*, *V. parahemolyticus*, *V. vulnificus*
- ? *Yersinia enterocolitica*

RG2 Fungal Agents

- ? *Blastomyces dermatitidis*
- ? *Cladosporium bantianum*, *C. (Xylohypha) trichoides*
- ? *Cryptococcus neoformans*
- ? *Dactylaria galopava* (*Ochroconis gallopavum*)
- ? *Epidermophyton*
- ? *Exophiala (Wangiella) dermatitidis*
- ? *Fonsecaea pedrosoi*
- ? *Microsporium*
- ? *Paracoccidioides braziliensis*
- ? *Penicillium marneffeii*
- ? *Sporothrix schenckii*
- ? *Trichophyton*

RG2 Parasitic Agents

- ? *Ancylostoma* human hookworms including *A. duodenale*, *A. ceylanicum*
- ? *Ascaris* including *Ascaris lumbricoides suum*
- ? *Babesia* including *B. divergens*, *B. microti*
- ? *Brugia* filaria worms including *B. malayi*, *B. timori*
- ? *Coccidia*
- ? *Cryptosporidium* including *C. parvum*
- ? *Cysticercus cellulosae* (hydatid cyst, larva of *T. solium*)
- ? *Echinococcus* including *E. granulosus*, *E. multilocularis*, *E. vogeli*
- ? *Entamoeba histolytica*
- ? *Enterobius*
- ? *Fasciola* including *F. gigantica*, *F. hepatica*
- ? *Giardia* including *G. lamblia*
- ? *Heterophyes*
- ? *Hymenolepis* including *H. diminuta*, *H. nana*
- ? *Isospora*
- ? *Leishmania* including *L. braziliensis*, *L. donovani*, *L. ethiopia*, *L. major*, *L. mexicana*, *L. peruviana*, *L. tropica*
- ? *Loa loa* filaria worms
- ? *Microsporidium*
- ? *Naegleria fowleri*
- ? *Necator* human hookworms including *N. americanus*
- ? *Onchocerca* filaria worms including, *O. volvulus*
- ? *Plasmodium* including simian species, *P. cynomologi*, *P. falciparum*, *P. malariae*, *P. ovale*, *P. vivax*
- ? *Sarcocystis* including *S. sui hominis*
- ? *Schistosoma* including *S. haematobium*, *S. intercalatum*, *S. japonicum*, *S. mansoni*, *S. mekongi*
- ? *Strongyloides* including *S. stercoralis*
- ? *Taenia solium*
- ? *Toxocara* including *T. canis*
- ? *Toxoplasma* including *T. gondii*
- ? *Trichinella spiralis*
- ? *Trypanosoma* including *T. brucei brucei*, *T. brucei gambiense*, *T. brucei rhodesiense*, *T. cruzi*
- ? *Wuchereria bancrofti* filaria worms

RG2 Viruses

- ? Adenoviruses, human - all types
- ? Alphaviruses (Togaviruses) - Group A Arboviruses
- ? Eastern equine encephalomyelitis virus
- ? Venezuelan equine encephalomyelitis vaccine strain TC-83
- ? Western equine encephalomyelitis virus
- ? Arenaviruses
- ? Lymphocytic choriomeningitis virus (non-neurotropic strains)
- ? Tacaribe virus complex
- ? Bunyaviruses
- ? Bunyamwera virus
- ? Rift Valley fever virus vaccine strain MP-12
- ? Caliciviruses
- ? Coronaviruses

- ? Flaviviruses (Togaviruses) - Group B Arboviruses
- ? Dengue virus serotypes 1, 2, 3, and 4
- ? Yellow fever virus vaccine strain 17D
- ? Hepatitis A, B, C, D, and E viruses
- ? Herpesviruses - except Herpesvirus simiae (Monkey B virus) (*Risk Group 4*)
- ? Cytomegalovirus
- ? Epstein Barr virus
- ? *Herpes simplex* types 1 and 2
- ? *Herpes zoster*
- ? Human herpesvirus types 6 and 7
- ? Orthomyxoviruses
- ? Influenza viruses types A, B, and C
- ? Papovaviruses
- ? All human papilloma viruses
- ? Paramyxoviruses
- ? Newcastle disease virus
- ? Measles virus
- ? Mumps virus
- ? Parainfluenza viruses types 1, 2, 3, and 4
- ? Respiratory syncytial virus
- ? Parvoviruses
- ? Human parvovirus (B19)
- ? Picornaviruses
- ? Coxsackie viruses types A and B
- ? Echoviruses - all types
- ? Polioviruses - all types, wild and attenuated
- ? Rhinoviruses - all types
- ? Poxviruses - all types except Monkeypox virus (*Risk Group 3*) and restricted poxviruses including Alastrim, Smallpox, and Whitepox
- ? Reoviruses - all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)
- ? Rhabdoviruses
- ? Rabies virus - all strains
- ? Vesicular stomatitis virus - laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow
- ? Togaviruses (see Alphaviruses and Flaviviruses)
- ? Rubivirus (rubella)

3. Risk Group 3 (RG3) Agents

RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available.

RG3 Bacterial Agents Including Rickettsia

- ? *Bartonella*
- ? *Brucella* including *B. abortus*, *B. canis*, *B. suis*
- ? *Burkholderia (Pseudomonas) mallei*, *B. pseudomallei*
- ? *Coxiella burnetii*
- ? *Francisella tularensis*
- ? *Mycobacterium bovis* (except BCG strain, *Risk Group 2*), *M. tuberculosis*
- ? *Pasteurella multocida* type B - "buffalo" and other virulent strains

- ? *Rickettsia akari*, *R. australis*, *R. canada*, *R. conorii*, *R. prowazekii*, *R. rickettsii*, *R. siberica*, *R. tsutsugamushi*, *R. typhi* (*R. mooseri*)
- ? *Yersinia pestis*

RG3 Fungal Agents

- ? *Coccidioides immitis* (sporulating cultures; contaminated soil)
- ? *Histoplasma capsulatum*, *H. capsulatum var. duboisii*

RG3 Parasitic Agents

None

RG3 Viruses and Prions

- ? Alphaviruses (Togaviruses) - Group A Arboviruses
- ? Semliki Forest virus
- ? St. Louis encephalitis virus
- ? Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83, RG2)
- ? Arenaviruses
- ? Flexal
- ? Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
- ? Bunyaviruses
- ? Hantaviruses including Hantaan virus
- ? Rift Valley fever virus
- ? Flaviviruses (Togaviruses) - Group B Arboviruses
- ? Japanese encephalitis virus
- ? Yellow fever virus
- ? Poxviruses
- ? Monkeypox virus
- ? Prions
- ? Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)
- ? Retroviruses
- ? Human immunodeficiency virus (HIV) types 1 and 2
- ? Human T cell lymphotropic virus (HTLV) types 1 and 2
- ? Simian immunodeficiency virus (SIV)
- ? Rhabdoviruses
- ? Vesicular stomatitis virus

4. Risk Group 4 (RG4) Agents

RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

RG4 Bacterial Agents

None

RG4 Fungal Agents

None

RG4 Parasitic Agents

None

RG4 Viral Agents

- ? Arenaviruses
- ? Guanarito virus
- ? Lassa virus
- ? Junin virus
- ? Machupo virus
- ? Sabia
- ? Bunyaviruses (Nairovirus)
- ? Crimean-Congo hemorrhagic fever virus
- ? Filoviruses
- ? Ebola virus
- ? Marburg virus
- ? Flaviruses (Togaviruses) - Group B Arboviruses
- ? Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr,
- ? Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses
- ? Herpesviruses (alpha)
- ? Herpesvirus simiae (Herpes B or Monkey B virus)
- ? Paramyxoviruses
- ? Equine morbillivirus
- ? Hemorrhagic fever agents and viruses as yet undefined

Phytopathogenic Agents (Flanders Interuniversity Institute for Biotechnologies, 2002).

A short list of some phytopathogens is given below. However, it is important to note that some phytopathogens are also subject to additional quarantine regulations that are designed to combat relevant plant diseases or diseases that can affect plant products. If your organism is not on this list, consult the lists at www.biosafety.be before concluding that your organism is not pathogenic.

Phytopathogenic viruses

Risk Group 2 phytopathogenic viruses

- ? Alfalfa mosaic virus
- ? Apple chlorotic leaf spot virus
- ? Apple mosaic virus
- ? Apple stem grooving virus
- ? Barley yellow mosaic virus
- ? Beet western yellows virus
- ? Carnation ringspot virus
- ? Cucumber mosaic virus
- ? Hop mosaic virus
- ? Maize dwarf mosaic virus
- ? Melon necrotic spot virus
- ? Papaya ringspot virus
- ? Pea early-browning virus
- ? Potato leafroll virus
- ? Potato virus
- ? Tobacco mosaic virus
- ? Tobacco necrosis virus
- ? Tobacco rattle virus
- ? Tobacco stunt virus
- ? Tomato mosaic virus

Risk Group 3 phytopathogenic viruses

- ? Lettuce mosaic virus
- ? Tobacco streak virus
- ? Tomato bushy stunt virus
- ? Tomato yellow leaf curl virus
- ? Wheat dwarf virus
- ? Wheat spindle leaf mosaic virus

Phytopathogenic bacteria and related organisms

Risk Group 2 Phytopathogenic bacteria and related organisms

- ? *Agrobacterium rhizogenes*
- ? *Agrobacterium rubi*
- ? *Agrobacterium tumefaciens*
- ? *Erwinia carotovora* subsp. *betavasculorum*
- ? *Erwinia chrysanthemi* pv. *chrysanthemi*
- ? *Erwinia salicis*
- ? *Erwinia tracheiphila*
- ? *Pseudomonas cichorii*
- ? *Pseudomonas fluorescens*
- ? *Pseudomonas syringae* subsp. *syringae*
- ? *Rhodococcus fascians*
- ? *Xanthomonas campestris* pv. *alfalfae*

Risk Group 3 Phytopathogenic bacteria and related organisms

- ? *Pseudomonas syringae* pv. *phaseolicola*
- ? *Pseudomonas syringae* pv. *pisi*
- ? *Xanthomonas campestris* pv. *aberrans*
- ? *Xanthomonas populi*

Phytopathogenic fungi

Risk Group 2 Phytopathogenic fungi

- ? *Alternaria dauci*
- ? *Botrytis allii*
- ? *Botrytis elliptica*
- ? *Botrytis hyacinthi*
- ? *Botrytis tulipae*
- ? *Cladosporium phlei*
- ? *Cladosporium variabile*
- ? *Claviceps purpurea*
- ? *Fusarium arthrosporioides*
- ? *Fusarium culmorum*
- ? *Fusarium gramineum*
- ? *Fusarium oxysporum* f. sp. *betae*
- ? *Fusarium oxysporum* f. sp. *pisi*
- ? *Glomerella cingulata* (*Colletotrichum gloeosporioides*)
- ? *Glomerella graminicola* (*Colletotrichum graminicola*)
- ? *Glomerella tucumanensis* (*Colletotrichum falcatum*)
- ? *Penicillium corymbiferum*

- ? *Penicillium cyclopium*
- ? *Penicillium digitatum*
- ? *Penicillium expansum*
- ? *Penicillium italicum*
- ? *Phytophthora infestans*
- ? *Phytophthora megasperma*
- ? *Rhizoctonia carotae*
- ? *Rhizoctonia fragariae*
- ? *Rhizoctonia tuliparum*
- ? *Rhizopus arrhizus*
- ? *Rhizopus stolonifer*
- ? *Sclerophthora macrospora*
- ? *Sclerospora graminicola*
- ? *Sclerotinia minor*
- ? *Sclerotinia trifoliorum*
- ? *Septoria azaleae*
- ? *Septoria lactucae*

Risk Group 3 Phytopathogenic fungi

- ? *Alternaria solani*
- ? *Botrytis fabae*
- ? *Claviceps gigantea*
- ? *Fusarium coeruleum*
- ? *Fusarium oxysporum* f. sp. *lycopersici*
- ? *Fusarium oxysporum* f. sp. *trifolii*
- ? *Fusarium solani* f. sp. *cucurbitae*
- ? *Fusarium solani* f. sp. *phaseoli*
- ? *Fusarium solani* f. sp. *lisi*
- ? *Mucor circinelloides*
- ? *Mucor piriformis*
- ? *Mucor racemosus*
- ? *Mucor strictus*
- ? *Septoria apiicola*
- ? *Septoria chrysanthemella*
- ? *Septoria lycopersici* var. *Lycopersici*

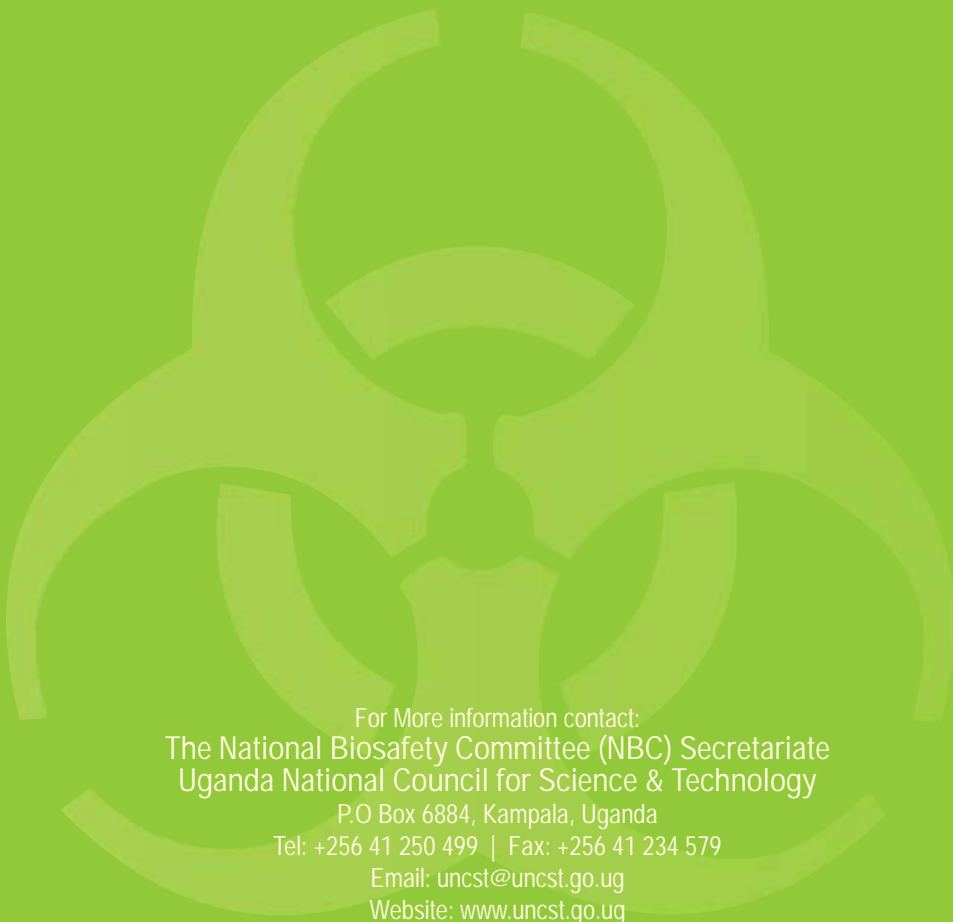
Phytopathogenic parasites

Risk Group 3 phytopathogenic parasites
Heterodera glycines

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