

Department of  
State for Forestry  
and the Environment

United Nations  
Environmental Programme  
(UNEP)

**Executing Agency:**  
Department of PARKS AND Wildlife Management  
Tel: (220) 4375 888  
Fax: (220) 439 2179

**National GEF Focal Point:**  
National Environment Agency (NEA)

## **Development of NATIONAL BIOSAFETY FRAMEWORK FOR THE GAMBIA**

Project No: GF/2716-01-4319  
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**Project Coordinator:**  
Mr. Alpha Jallow, DPWM, Gambia

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## Abbreviations and Acronyms

DNA	De-oxyribose Nucleic Acid
DOSE	Department of State for Education
DOSH	Department of State for Health
DPWM	Department of Parks and Wildlife Management
GBA	Greater Banjul Area (GBA)
GEF	Global Environment Facility
GMM	Genetically Modified Micro-organisms
GMOs	Genetically Modified Organisms
GMP	Good Microbiological Practice
GMSC	Genetic Modification Safety Committees
GNBSA	Gambia National Biosafety Authority
GOSH	Good Occupational Safety and Hygiene
GRTS	Gambia Radio and Television Services
IEC	Information, Education and Communication
ITC	International Trypanotolerance Centre
MRC	Medical Research Council
NaNa	National Nutrition Agency
NARI	Natural Resources, Research Institutions (NARI,
NBSAP	National Biodiversity Strategy and Action Plan
NBTC	National Biosafety Technical Committee
NCC	National Coordination Committee
NEA	National Environment Agency (NEA)
NEMC	National Environment Management Council
NGOs	Non-Governmental Organizations
UNEP	United Nations Environment Programme
WID	Women in Development Project

# 1. INTRODUCTION

In recognition of the worldwide biological diversity situation, The Government of The Gambia signed the Convention on Biological Diversity (CBD) on the 12<sup>th</sup> June 1992 and ratified it on June 10<sup>th</sup> 1994 and signed the Cartagena Protocol on Biosafety on 10<sup>th</sup> April 2002 and ratified the Protocol on the 2<sup>nd</sup> July 2003. In fulfillment of the obligations of CBD parties under Article 6 of the Convention, The Gambia prepared a Biodiversity Strategy and Action Plan (NBSAP) in 1999. In its cross-sectoral action plans, the NBSAP envisaged access to technology and handling of biotechnology and, proposed the elaboration of a Biosafety Framework.

To implement the NBSAP action plan on access to technology and handling of biotechnology and in fulfillment of its obligations under Article 1 of the Cartagena Protocol, the Government of The Gambia sought and obtained project assistance under the UNEP/GEF Project on the Development of National Biosafety Frameworks. The sub project: Development of National Biosafety Framework for The Gambia, number GFL-2328-2716-4384 started on 20<sup>th</sup> March, 2002 for an approved duration of 18 months, ending 20<sup>th</sup> September 2003. However, due to delays in project start-up it was extended for a nine months period.

The Department of Parks and Wildlife Management (DPWM) under the Department of State for Forestry and Natural Resources is the designated executing agency for the project. The Assistant Director, Mr. Alpha O.Jallow has been appointed as National Coordinator for the Project with the following postal address:

Department of Parks & Wildlife Management  
Abuko Nature Reserve  
Banjul, The Gambia..or  
P.O.BOX 5447, Brikama, The Gambia.

To facilitate the effective implementation of the project, a National Coordination Committee (NCC) and a Task Force on Biosafety were constituted in 2003. The NCC comprises members from the following institutions:

<b>Member</b>	<b>Institution</b>
Mrs. Fatou Kuyateh	DOSFNR&E, Permanent Secretary
Mr. Momodou Kotu Cham	National Environment Agency(Chairperson)
Mr. Kebba Bojang	National Environment Agency(ANR Coordinator)
Mr. Momodou Sarr	National Environment Agency
Dr. Almamy Camara	Department of Parks and Wildlife Management(Director)
Mr. Alpha Jallow	Department of Parks and Wildlife Management(Deputy Director)
Mr. Momodou Kassama	Department of Parks and Wildlife Management(Senior Wildlife Conservation Officer)
Mr. Lamin Jobarteh	West African Bird Study Association(Executive Director)
Mr. Abba Gibba	Department of Community Development

Mr. Famara Darboe	Department of Fisheries(Principal Fisheries Officer)
Mr. Lamin MS Jobe	National Agricultural Research Institute
Mr. John Peacock	Department of Water Resources
Mr. Ebrima A Secka	Agricultural Pest Management Unit
Mr. Graigg Emms	Makasutu Wildlife Trust
Mr. Mamour Sey	Radville Farms
Mr. Chernoo Joof	Office of The President
Dr. Henry Carrol	Anthony General's Chambers
Mohamed T. Bobb	Department of Livestock Services
Lang Kinteh	Department of Agricultural Services
Lamin Bojang	Department of Forestry
Magreth Mendy	National Environment Agency
Kawsu Manjang	Department of Parks and Wildlife Management
Dr. Mariatou Jallow	Department of Medical Services
Isatou Semega Janneh	Natuonal Nutrition Agency
Momodou Jallow	Department of Planning
Jean Thomas	Medical Research Council
Eric Hoeven	International Trypanotolerance Centre

The Task Force on Biosafety was assigned with preparing the relevant thematic reports and comprised membership from the following institutions:

<b>Member</b>	<b>Institution</b>
Kebba Bojang	National Environment Agency
Ebrima A.Secka	Agricultural Pest Management Unit, Department of Agricultural Services
Mohamed T. Bobb	Department of Livestock Services
Dr. Henry Carrol	Attorney General's Chamber
Therese Sarr	Attorney General's Chamber
Dr. Linda Barnett	Makasutu Wildlife Trust
Lamin Bojang	Department of Forestry
Lamin Jarjusey	Department of Community Development
Mamour Sey	Radville Farms
Dr. Mariatou Talla Jallow	Department of State for Health
Momodou L. Kassama	Department of Parks and Wildlife Management
Famara Darboe	Department of Fisheries
Lamin M.S Jobe	National Agricultural Research Institute
Kutubo Sanyang	National Agricultural Research Institute
Momodou O.Jallow	Department of Planning of Agriculture
Alpha Omar Jallow	Coordinator, Department of Parks and Wildlife Management

## **2. BIOSAFETY POLICIES**

### **2.1 Existing Government Policies**

While a series of sectoral policies exists, the ones most relevant to biosafety and biotechnology issues include the following:

- (i) Agriculture and Natural Resources Sector (including arable agriculture, fisheries, forestry, livestock, water resources and parks & wildlife management) policies;
- (ii) Health policies, and;
- (iii) Environment Policies.

#### **Agriculture and Natural Resources policies**

The current agriculture and natural resources sector policy is to increase overall agricultural production and productivity consistent with a rational exploitation of the natural resources base on sustainable basis. The policy problem is manifested in low farm incomes, growing rural poverty and household food insecurity, accelerated rural – urban drift and rapid environmental degradation. The medium term agriculture and natural resources policy goals include:

- (i) achieve national food self-sufficiency and security through the promotion of sustainably diversified food production programs with emphasis on cereal production to contain the growth of imported rice;
- (ii) increase overall sector's output especially of domestic food and export products in order to ensure food security and enhance foreign earning capacity to finance other aspects of the development process;
- (iii) create employment and generate income for the majority of the rural population who are dependent on primary production particularly women, youth and producer associations;
- (iv) diversify the production base to facilitate the production of a wide range of food and export crops in order to minimize the fluctuations and uncertainties in household incomes and export earnings;
- (v) reduce disparities between rural and urban incomes as well as between men and women, curb rural-urban drift and accelerate the space of rural sector development;
- (vi) provide effective linkages between the agriculture and natural resources sector and other sectors of the economy particularly the tourism sector so as to enhance their complimenting and supplementing synergy on a sustainable basis, and;
- (vii) ensure the judicious and sustainable exploitation of the country's natural resource base so as to conserve and improve biodiversity and enhance its productivity consistent with consideration of the needs and rights of future generations.

## Environmental Strategies

Sustainable economic growth and development consistent with improvement in the quality of life for the present generation without compromising the rights of future generations is the corner stone of the government's environmental policy. The following environmental policy objectives of the **Gambia Environmental Action Plan (GEAP)** will provide the government's medium term operational guidelines for the protection, management, exploitation and utilization of environmental resources. The policy objectives include the following:

- (i) to conserve and promote the rational use of natural resources for the benefit of the present and future generations;
- (ii) to protect and improve the health and quality of life of all Gambians through sound environmental management;
- (iii) to preserve and restore the equilibrium of ecological processes;
- (iv) to strengthen the institutional framework for environmental coordination and management at national, regional and global levels;
- (v) to increase environmental awareness and understanding of the public and bring about effective public participation and community involvement in its management;
- (vi) accelerate the adoption of alternative sources of renewable energy; and,
- (vii) to ensure the effective integration of environmental considerations in all development strategies and related activities.

## 2.2 National Biosafety Policies

No biosafety-specific stand-alone policy exists in The Gambia. However, a cursory review of the foregoing agriculture and natural resources and environmental policy stances will quickly reveal that they constitute an adequate objective framework for a biosafety policy which aims at harnessing the output of modern biotechnology research in the quest for sustainable agricultural production and productivity, sound environmental protection and management and adequate health for all at all times. Thus a biosafety stand-alone policy objective framework would *inter alia*, include:

- (i) achieve national food self-sufficiency and security through the promotion of sustainably diversified food production technologies including the safe use of genetic engineering;
- (ii) promote the conservation, evaluation and sustainable utilization of biological and genetic resources, community knowledge and technologies;
- (iii) to recognize that all forms of life are the basis for human survival and therefore the appropriation of any life form or derivative thereof violates the fundamental human right to life;

- (iv) to streamline the various acts and legislation for the restricted use, voluntary release in the environment, the importation and marketing and the exportation and transit handling of GMOs/GMO by-products;
- (v) to establish a reliable and transparent system of risk evaluation of GMO and GMO by-products;
- (vi) increase the overall agriculture and natural resources sector's output especially of domestic food and export products in order to ensure food security and enhance foreign earning capacity to finance other aspects of agriculture and natural resources and/or rural development process;
- (vii) promote improvements in the productivity, profitability, stability and sustainability of the major production systems through yield enhancement and maintenance of biological diversity;
- (viii) provide adequate mechanisms for guaranteeing the just, equitable and effective participation of all Gambians in the protection of their individual and collective rights and in making decisions which affect the country's biological and intellectual resources as well as the activities and benefits derived from their utilization,
- (ix) diversify the production base in order to facilitate the production of a wide range of food and export crops in order to minimize the fluctuations and uncertainties in household incomes and export earnings;
- (x) where necessary, to develop local capacity for genetic research and effectively use the products of these research with adequate safety measures through the enactment of appropriate legislation and risk assessment systems;
- (xi) reduce gender disparities in the sharing of benefits accruing from access to biological or genetic resources and community knowledge/technology in order to accelerate the space of rural sector development;
- (xii) provide effective linkages between the agriculture and natural resources sector and other sectors of the economy particularly the tourism sector so as to enhance their complimenting and supplementing synergy on a sustainable basis;
- (xiii) to recognize and protect the rights of local communities over their biological resources, knowledge and technologies that represent the very nature of their livelihood systems evolved over generations of human history;
- (xiv) ensure the judicious and sustainable exploitation of the country's biological or genetic resource base so as to conserve and improve biodiversity and enhance its productivity consistent with consideration of the needs and rights of future generations.
- (xv) promote the supply of good quality seed and planting material to farmers; and,
- (xvi) ensure that the biological or genetic resources are utilized in an effective and equitable manner in order to strengthen food security in the Gambia.

### **2.2.1 Research & Development-Challenges and Constraints**

Biotechnology research and development in the Gambia can contribute substantially to sustainable development through the development of better health care systems and services,

ensuring food security, improved supplies of portable water, more efficient industrial development processes for transforming raw materials into finished products, support for sustainable methods of afforestation and reforestation and detoxification of hazardous wastes. Notwithstanding these opportunities, the agriculture and natural resources sector's production and productivity and its overall contribution to exports have been on the decline due to adverse climatic, domestic production and international market conditions and factors. Thus the medium- to long-term contribution of biosafety will be in the reduction of rural poverty and improved national food security by enhancing the provision of an enabling framework for greater private sector (both internal and external) participation, diversification of the production base, increasing domestic savings, stemming rural-urban migration, sustaining a healthy environment and protecting and controlling natural resource degradation as well as mainstreaming gender equity in the development process. The major constraints that will militate against the realization of these policy objectives in the medium-term include:

- (i) lack of a critical mass of trained manpower specialized in the various disciplines of genetic engineering to ensure the development of improved varieties/breeds and the rapid production of adequate food to feed the country's rapidly increasing population;
- (ii) inadequate or inappropriate infrastructure and facilities (laboratory buildings and equipments) to handle simple micro-propagation/tissue culture;
- (iii) inappropriateness of research topics/materials related to traditional food crops of importance to the Gambia and the sub-region;
- (iv) limited public awareness, education and participation in Biotechnology/Biosafety resulting in serious constraints to biotechnology development, use, evaluation/monitoring and release of GMOs and by-products in The Gambia.

### **2.2.2 Solutions to Overall Sector-Wide Constraints**

The Government will address the overall Biosafety constraints through a strategy of Government, Community and Private sector partnership in ensuring the provision of adequate mechanisms for guaranteeing the just, equitable and effective participation of all Gambians in the protection of their individual and collective rights and, in making decisions which affect the country's biological and intellectual resources as well as the activities and benefits derived from their utilization. Such a biosafety strategy framework will be aimed at mitigating these constraints through:

- (i) alerting the Gambian public especially farmers of the consequences of the rapid growth and development of biotechnological innovations on the future of traditional farming systems;
- (ii) informing and stimulating discussions among the various categories of stakeholders on GMOs and on agricultural related aspects of intellectual and community property rights;
- (iii) facilitating access to information on biotechnological research and development such as research on GMOs and by-products, regulations on containment and

- control measures, GMO risk evaluations and assessments procedures and intellectual and community property rights;
- (iv) establishing a policy of **precaution** against the risks or uncertainties associated with GMOs and GMO by-products with the context of the socio-economic environment of the country and the sub-region;
  - (v) developing alternative scientific and agricultural policies with regard to transgenic crops designed to ensure national food security;
  - (vi) developing a strategy for the control of modern aspects of biotechnological research and development (including genetic engineering, molecular biology etc and determine the stakes involved in biodiversity and biosafety;
  - (vii) disseminating information on the **African Model Law** for the protection of the rights of local communities (including farmers' rights) and breeders' rights for the regulation of access to biological or genetic resources;
  - (viii) ensuring that biological or genetic resources are utilized in an effective and equitable manner in order to ensure the sharing of benefits and strengthen national food security; and,
  - (ix) promoting and encourage the building of in country scientific and technological capacity (including community level capacities) associated with the conservation and sustainable use of biological or genetic resources.

### 2.2.3 Other Policy Issues

Other policy challenges that require urgent attention relate to intellectual property rights. The issue of intellectual property rights has in more recent years led to the commercial exploration of biodiversity. Patents have sometimes been used to judge the investment value of companies. On the pretext of patent infringement, industrial companies in the developed world have prevented companies in developing countries from producing or acquiring cheaper generic drugs to combat public health care crises such as HIV/AIDS and effectively alienated the interests of farmers and local communities who hitherto gathered indigenous knowledge on plants and crops over centuries and as a way of life. Therefore the legal framework for Biosafety should necessarily include the issue of intellectual property rights that will generally protect the collective rights of Gambian farmers and local communities. It is within this perspective that the **“African Model Law for the Protection of the Rights of Local communities, Farmers and Breeders and, for the Regulation of Access to Biological Resources”** is proposed for adoption in The Gambia.

The model law which is designed to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, knowledge and technologies in order to maintain and improve their diversity as means of sustaining all life support systems has the following specific objectives:

- (i) to recognize, protect and support the inalienable rights of local communities (including farmers) over their biological resources, knowledge and technologies;
- (ii) to recognize and protect the rights of breeders;

- (iii) to provide an appropriate system of access to biological resources, community knowledge and technologies subject to the prior informed consent of the state and the affected local communities;
- (iv) to promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, knowledge and technologies;
- (v) to ensure the effective participation of the concerned communities in making decisions as regards the distribution of benefits which may be acquired from the use of their biological resources, knowledge and technologies;
- (vi) to promote and encourage the building of national and grassroots scientific and technological capacity relevant to the conservation and sustainable use of biological resources;
- (vii) to provide appropriate institutional mechanisms for effective implementation and enforcement of the rights of local communities (including farmers), breeders and the conditions of access to biological resources, community knowledge and technologies;
- (viii) to promote the conservation, evaluation and sustainable utilization of biological resources;
- (ix) to promote improvements in the productivity, profitability, stability and sustainability of major production systems through yield enhancement and maintenance of biological diversity;
- (x) to promote the supply of good quality seed/planting materials to farmers; and,
- (xi) to ensure that biological resources are utilized in an effective and equitable manner in order to strengthen the food security of the nation.

## 2.2.4 Access to Biological Resources

Individuals and companies accessing biological resources (including protected areas), knowledge and technologies of local communities in any part of the Gambia shall be subject to an application for the prior informed consent and written permission of the local communities and the Gambia National Biosafety Authority. It is expected that applications for access to biological resources, indigenous knowledge and technologies shall contain information such as:

- (i) the identity of the applicant and the documents that testify to his/her capacity to enter into contract (including the identity of all partners with the contracting party);
- (ii) the resources to which the access is being sought (including the specific location from which the resources is to be collected), its present and potential uses, the sustainability of the removal of the genetic resource and the potential risks associated from access to the resource;
- (iii) will collection of the resource endanger any component of biological diversity and potential risks which may emanate from the access;
- (iv) the purpose for which access to the resource is requested including the type and extent of the research to be undertaken and the teaching or commercial potentials to be acquired;
- (v) a description of the manner and extent of local and national collaboration in the research and development of the biological resource;
- (vi) the identification of the national institution(s) which will participate in the research and be responsible for the monitoring the research process;
- (vii) a detailed description of the location where the research and development activities is expected to be undertaken;
- (viii) the primary and possible subsequent destination(s) of the biological resource;
- (ix) the benefits (economic, social, scientific and environmental benefits) that are expected to accrue to the country and local communities from which the biological or genetic resource was collected;
- (x) the proposed mechanisms and arrangements for benefit sharing;
- (xi) the description of the innovation, practice, technology associated with the genetic resource; and,
- (xii) in cases where large quantities of biological resources are collected, a provision to undertake environmental impact assessment to cover at least three generations.

## 2.2.5 Requirements for Consultations

Approval to begin research and development work involving biological or genetic resources must be sought on formal applications which will be subjected to adequate consultations with all parties and such consultations shall be coordinated by the National Biosafety Authority/NEA. Access undertaken without prior consultations and approval of the concerned

parties shall be considered as invalid and shall be subject to penalties, which shall be spelt out, in the legislative document.

The completed application form will be placed in a public registry, gazette, Biosafety website and the print and electronic media for comments by the general public and other interested individuals or parties prior to the granting of access permits by GNBSA. Signed written agreements between the GNBSA as the competent authority, the affected local communities and the applicant or collector shall serve as mechanism of conveyance of approvals or permits which shall place the following commitments on the collector:

- (i) to adhere to the limits set by the agreement relating to the quantity and quality of the biological or genetic resource to be collected;
- (ii) to guarantee to deposit duplicates of all biological or genetic resources, records of community innovation, practice, knowledge and technologies with complete field information on each specimen of the biological or genetic resource with the national competent authority (GNBSA). Such information shall be deposited with the local community if so required;
- (iii) to immediately inform all the parties concerned of the findings from the research and development activities associated with the biological or genetic resource undertaken;
- (iv) not to transfer the biological or genetic resource or any of its derivatives or the community innovation, practice, knowledge or technology to third parties without proper authorization from GNBSA and the affected local communities;
- (v) the applicant shall not apply for any form of intellectual property right protection over the biological or genetic resource or its derivatives including community innovation, practice, knowledge and technologies without the prior consent of the all the parties;
- (vi) institute sufficient mechanisms or arrangements for benefit sharing between all the parties including local communities;
- (vii) access to the biological or genetic resource shall be conditioned upon a commitment to for the applicant to contribute to the State and the local community in the regeneration and conservation of the biological or genetic resources;
- (viii) applicant must agree to submit to GNBSA a regular status report of research and development on the affected resource and in the case of large scale extraction, the applicant must agree to provide a status report on the affected ecological system;
- (ix) the applicant must agree to abide by the relevant laws of the country especially those associated with sanitary control, Biosafety and the protection of the environment in addition to adhering to the cultural practices, traditional values and the customs of the local communities; and,
- (x) the applicant must ensure that all research activities are conducted in-country with the active participation of local experts and collaborating institutions.

## **2.2.6 Patents over Life forms and Biological Processes**

It is proposed that no request shall recognize applications for patents over life forms and biological processes in the Gambia and therefore any application on patents covering life forms or biological processes shall not be entertained. Applications for patents over life forms and biological or genetic resources associated with the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology shall not be applied for under any legislation in the Gambia. GNBSA shall be the only authority to approve the granting of access to a biological or genetic resource or the community innovation, practice, knowledge or technology with attached condition as it deems necessary. However, the granting of such permits shall be preceded by prior consultations with the affected communities and the authority shall ensure that such community agreements are provided willingly.

## **2.2.7 Conditions Related to Academic and Research Institutions and Public/Inter-Governmental Agencies**

Academic and research institutions, public and inter-governmental agencies wishing to undertake biotechnological research and development work in the Gambia must also seek the permission of the GNBSA through the submission of a written application and the granting of such permission shall be based on the prior consent of the affected community. The application for access for research purposes shall clearly state the objective of the research and the relation of the applicant to the industry. Materials and information collected in the research process shall not be transferred to any other party without an approved material transfer agreement. The government and/or the community shall reserve the prior rights to endorse or reject the material transfer agreement. A change of functions from purely research to predominantly commercial shall cause the GNBSA to vary accordingly its terms and conditions attached to the request to access biological or genetic resources, knowledge and technologies within local communities in the Gambia.

## **2.2.8 Benefit Sharing**

The access permit to be provided by the GNBSA should provide for the payment of benefits to the affected communities and the State prior to the commencement of work. The fee to be paid shall vary depending on the type of the permit (academic research, commercial research or commercial exploitation), the amount of samples to be collected, geographic location, and the duration of the collection and the nature of the permit. The State and the affected communities shall be entitled to a share of the earnings when any biological or genetic resource and/or knowledge collected generate income (directly or indirectly) from a product used in production process.

The GNBSA shall grant the applicant/collector the appropriate permit for access following a thorough examination of the application and after ascertaining that the affected communities have duly provided their consent. The authority shall provide one of the following types of permits (i) an academic research permit (ii) a commercial research permit or (iii) a commercial

exploitation permit. Academic research institutions, public and inter-governmental agencies cannot be in possession and use two types of permits at the same time for the same resource unless the GNBSA provides a written permission to the effect. This provision is not in any way intended to limit the GNBSA's powers to issue any other type of access permit. Therefore, the GNBSA may unilaterally withdraw its consent hitherto provided to the applicant/collector and repossess the written permit under the following conditions:

- (i) The existence of a violation by the applicant/collector of any of the conditions contained in the Biosafety legislation;
- (ii) The existence of a failure on the part of the applicant to comply with agreed terms;
- (iii) The existence of failure by the applicant to meet the conditions of access;
- (iv) Reasons of over riding public interest; and,
- (v) The need to protect the environment and biological diversity.

A termination or withdrawal of consent by the GNBSA shall be done in consultation with the concerned local communities. The reasons for such termination or withdrawal of consent or permits should be fully explained to and understood by the affected communities. Such withdrawal or termination of permits of consent shall be placed on the Biosafety website and other available channels of communication. The GNBSA shall accordingly inform the secretariat of the Cartagena protocol of its decisions.

### **2.2.9 Restrictions on Activities Related to Access**

The GNBSA shall establish restrictions or prohibitions to the introduction on those activities which are directly or indirectly associated with access to biological or genetic resources based on the following conditions:

- (i) the biological or genetic resources are found to be endangered;
- (ii) the biological or genetic resources are rare;
- (iii) the collection of the biological or genetic resources has adverse effects upon human health or upon the quality of life or the cultural values of local communities;
- (iv) the collection of the biological or genetic resources has adverse environmental impacts which are undesirable or difficult to control;
- (v) the uncontrolled collection of the biological or genetic resources has adverse effects resulting in genetic erosion or loss of ecosystems;
- (vi) the applicant or collector of the biological or genetic resources does not comply with rules on biosafety or food security; and,
- (vii) the applicant or collector of the biological or genetic resources is found to be using the resources for purposes contrary to the national interest.

### **2.2.19 Institutional Arrangements**

The Government of The Gambia shall with the designation of the National Environment Agency (NEA) as the Gambia National Biosafety Authority (GNBSA), implement and ensure the enforcement of the following duties:

- (i) create and operate a regulatory mechanism that will ensure effective protection of community intellectual property rights and regulation of access to biological resources;
- (ii) create an enabling environment for consultations and participation of local communities (including farming communities) in the identification of their rights as provided for under the customary laws and practices of the communities;
- (iii) identify types of community intellectual rights including farmers' rights;
- (iv) identify and define the requirements and procedures necessary for the recognition of community intellectual property rights;
- (v) develop criteria and mechanisms to standardize procedures,
- (vi) develop a system of registration of items protected by community intellectual rights (including farmers' rights) according to their customary law and practices;
- (vii) issue permits or license for the exploitation and commercialization of biological resources, including protected species, varieties or lineages, and community innovation, practices, and technologies; and,
- (viii) identify relevant technical institutions (including NGOs) that will assist local communities in the categorization of their biological resources, innovations, practices, knowledge and technologies.

### **2.2.20 Establishment and Functions of Inter-Sectoral Coordinating Body**

The Government of the Gambia will also establish an inter-sectoral National Biosafety Technical Working Group (NBTWG) which will assist the inter-sectoral coordinating functions of the NEA as the GNBSA. The NBTWG will secure high level representatives from relevant public sector institutions, professional organizations, NGOs and Community Based Organizations (CBOs) to coordinate and follow-up the proper implementation of these regulations. The functions of the NBTWG for the "Protection of the Rights of Local Communities and Breeders and for the Regulation of Access to Biological Resources" shall include the following:

- (i) ensure that the minimum conditions for the agreements with collectors are strictly observed and complied with;
- (ii) ensure that the rights of local communities are always protected through the verification of the requirements of prior informed consent by the local communities with due regard for gender equity;

- (iii) recommend policies and laws on the sustainable use of biological resources including new laws on intellectual property rights and community intellectual rights; and,
- (iv) perform any other such functions as may be necessary for effective implementation of these regulations.

### 3. REGULATORY REGIME

The adoption of advanced techniques in biotechnology is of major importance to many Africa countries due to the possibility of its contribution to sustainable development through the development of better health care systems and services, ensuring food security, improved supplies of portable water, more efficient industrial development processes for transforming raw materials into finished products, support for sustainable methods of afforestation and reforestation and, detoxification of hazardous wastes. However successful exploitation of these potentials of biotechnology are not without risks of adverse or negative effects. There is a thus a need for a well-conceived regulatory regime for the sustainable harnessing of these potentials.

There is no holistic legislation in The Gambia which addresses the critical issues of safe transfer, handling and use of Living Modified Organisms (LMO) resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking also into accounts risks to human health. However a number of legislation exist currently which address some important aspect of the subject if only incidentally, as it relates to agricultural development programmes (such as conventional agronomic crop evaluation and research, regulatory agricultural extension and farmer training, animal health; and, the promotion and dissemination of agricultural inputs including agricultural credit), public health, Biodiversity conservation and the control of the importation of pharmacologically active products (vaccines), plant and animal products. These legislations include:

- (i) **The Public Health Act** which empowers the **Minister (now Secretary of State-SOS)** responsible for Health to make regulations on matters of public and environmental health was adopted in 1990 and it effectively repealed the public Health Act of 1935 but maintained all the regulations made under the act.
- (ii) **Food safety Act (2005)**
- (iii) The Medicines Act which defined medical products as **“any article or substance intended to prevent, diagnose, alleviate or cure illness or symptoms of an illness in human or animals”** was adopted in 1984. The act makes provision for the manufacture, import, storage, distribution and use of registered medical products. The Department of State for Health and Medical Services imports and distribute large quantities of GMOs in form of vaccines but there is no regulatory body responsible for monitoring the safety of these products.
- (iv) **The plant importation and regulation act of 1936** provides the regulatory framework for the importation and exportation of plants, seeds, soil, manure or other plant packaging materials. The act specifically empowers the head of **the Agricultural Pest management Unit (APMU) of the Department of State**

- For Agriculture (DOSA)** to provide import and export permits to all importers and exporters of plants or plant products intended for commercial, private or public use. The act is specifically designed to prevent the import of plants, seeds, soil, manure and other plant packaging material that may be infected by disease.
- (v) The forest act (1977) empowered the Minister (SOS) to make regulations for the protection, control and management of forests in the Gambia. The act further provides that the SOS is **the only** authority empowered to give written permission for the export of forest produce.
  - (vi) **Wildlife Conservation Act (1977) and Wildlife Policy and Legislation (1999)**  
The Wildlife Conservation Act (1977) and the Wildlife Policy and legislation (1999) are perhaps the only legal instruments which have a definitive impact on biological diversity. Both the act and policy and legislation provide for the protection, conservation and sustainable use of wildlife and encourage the maintenance of minimum stock of vulnerable species through protection. It further stipulates that optimum returns of ecological, cultural, aesthetic, scientific and economic gains are incident to proper biodiversity management.
  - (vii) The National Environment Policy and Act which was enacted on the 27<sup>th</sup> May 1994 established the **National Environment Management Council (NEMC)** with the President of the Republic of The Gambia as the chairman of the council. Despite the inadequacy of the policy and act as it relate to Biosafety, among other things, the act is designed to ensure the following: (i) integrate the conservation and sustainable utilization of biological diversity (ii) prohibit or restrict any trade or traffic in any component of biological diversity (iii) prohibiting or controlling the production of alien species; and, (iv) the safe introduction of alien species of fauna and flora into the ecosystem.

### 3.1 The Objectives of the Regulatory Regime

The establishment and maintenance of an efficient Biosafety framework requires transparent and reliable procedures including information dissemination and public participation in the entire decision making process. It also calls for sensitization and coordination of activities between Departments of State, the University and research institutions, the private sector and the public. Considerable investments will be required to build modern laboratories and equipped them with modern scientific equipments and in some cases rehabilitate existing laboratories and provide the necessary equipments in order to reinforce their scientific and technical capacities. The proposed act/legislation should have the following objectives:-

- (i) Provide opportunity for the use of the benefits of modern scientific research (particularly in the area of biotechnology) in improving agricultural productivity, ensuring the continued use of genetic resources for the benefit of humanity and also taking advantage of the gene research for the benefit of the health sector,

- (ii) Ensuring that the health and well being of human and animals and the environment are protected from the hazards of the import, use and handling, distribution and marketing of GMOs and GMO by-products,
- (iii) Provide an independent choice for consumers in the use of GM and non-GM foods and prevent fraudulent declaration by marketing agencies,
- (iv) Encourage information dissemination, public participation and good governance,
- (v) Streamline the various acts and legislation for the restricted use, voluntary release in the environment, the importation and marketing and the exportation and transit handling of GMOs and GMO by-products;
- (vi) Maintain a balance between control of access to genetic resources and conservation of biological diversity and the overall need for environmental safety and protection; and,
- (vii) Establish a reliable and transparent system of risk evaluation of GMO and GMO by-products.

### **3.2 Organizational and Management Structures of the Regulatory Regime**

There exist two options for developing the necessary legislations pertaining to the work with Genetically Modified Organisms in the Gambia and these are: (i) to amend the existing legislation to include work with GMOs or (ii) draft new set of legislation for work with GMOs covering all relevant spheres of GMO activity. It is proposed to develop a set of new legislation considering that the current legislations are not cross-cutting enough to cover all aspects of agriculture, natural resources, environment and health. The new legislations being proposed will be designed to cover all aspects of GMO research and development. The guidelines proposed will be subject to the new Gambian legislation on Biosafety and need to be used alongside with relevant new legislations to be submitted to the National Assembly for approval.

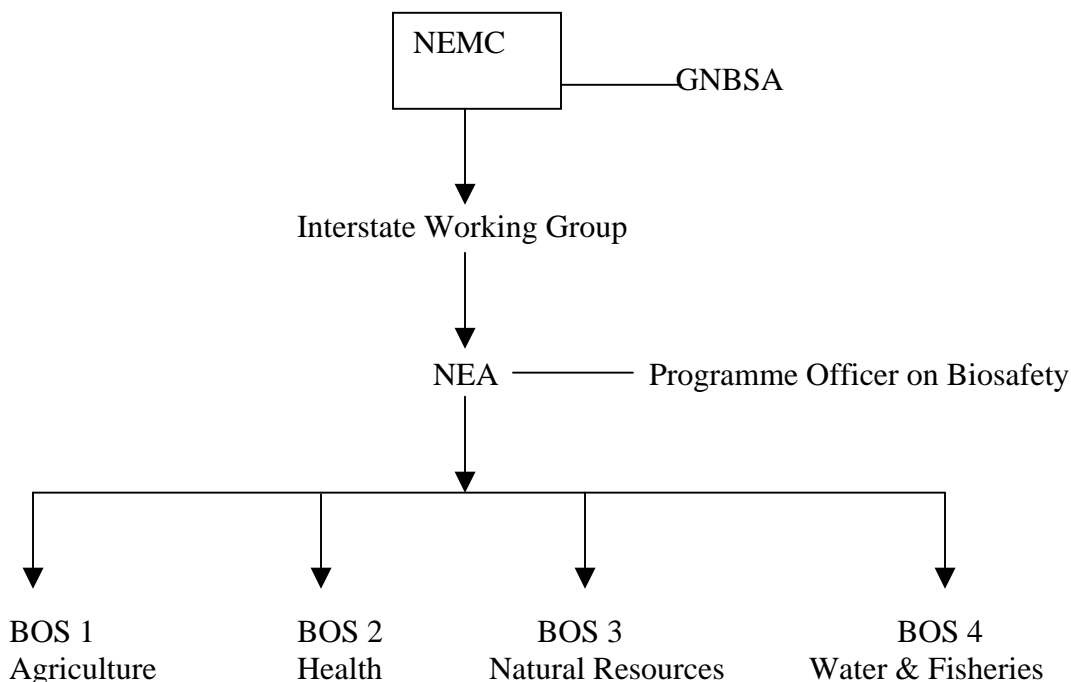
In the absence of explicit GM regulations in the Gambia, the proposed GMO containment and control measures and general guidance are based on experiences elsewhere. For instance, GMO Contained Used Regulations 1992 (UK) is included in this section but with substantial modifications to address the needs of The Gambia. It contains quite a lot of useful and relevant guidance for all workers coming in contact with GMO or GMO by-products.

It is proposed that the **Gambia National Biosafety Authority (GNBSA)** be established as a suitable institutional model to serve as the Advisory Committee on Genetic Modification (ACGM) and shall be established by an act of Parliament as part of the legal requirements for the establishment of a National Biosafety Framework. The ACGM or GNBSA's primary responsibility is to advise the Director of Medical and Health Services on the human health and safety aspects of the contained used of GMOs. It also advises the Secretaries of State responsible for the environmental matters on the environmental aspects of GM work. The

ACGM or GNBSA will also advise the Secretary of State for Agriculture on issues relating to agriculture related biotechnological research and development activities including the application of transgenic farm animals and their associated risks.

The Gambia National Biosafety Authority as the Advisory committee on Genetic Modification will address strategic and policy issues without the need to devote substantial time and energy on technical matters. Instead, the Gambia National Biosafety technical Committee will cover the technical aspects of all GM research and development activities in the Gambia including other aspects such as the control of import and marketing of GM products. The figure below presents the various components of the management mechanism.

**Figure1: Organogram of the NEMC and the its Components**



### **Management Responsibilities**

In organizations where genetic manipulation is undertaken, it will be management’s responsibility to ensure that the working environment is safe and conducive. It is expected that institutions undertaking genetic manipulation will establish Biosafety Management Committees. The responsibility of care to prevent risk to the health of the employee cannot be delegated as a responsibility of the workers. This obligation is not withstanding the obligation of the employee to take reasonable care for their own health and safety and that of others who may be affected by their acts or omissions in the routine performance of their duties.

It is therefore obligatory on management to monitor and take into consideration the activities of the Biosafety Officers and Genetic Modification Safety Committees which are mechanisms

designed to advise management on the risks and the control measures. Management should also constantly keep under review its policies and the status of effectiveness of the control measures. The **Containment Use Regulations (CURs)** by design places extensive statutory duties on employers to ensure the safety to both human health and the environment. The full details of the duties of employers are stipulated in the regulations and guidance (pages ....). A summary of the expected duties to be performed by the employer include the following:

- (i) The employer is expected to undertake risk assessments in areas of risk to human health and the environment. It should be noted that risk assessment for environmental safety covering GMOs that are not Micro-organisms (eg. transgenic animals) must be undertaken under GMO risk assessment procedures;
- (ii) The employer undertaking GM work shall be required to provide risk assessments for both human health and the environment. The organization or individual shall by regulatory provisions appoint a Genetic Modification Safety Committee to provide regular advise on the risks and control measures;
- (iii) The employer will ensure that adequate containment facilities and procedures are established to minimize risk to the workers and the environment;
- (iv) The employer is expected to provide and test containment equipment at appropriate intervals and where necessary to undertake monitoring for the presence of process organisms outside of the containment area;
- (v) Establish a well planned training program and provide such training to relevant employees commensurate with the level of the risk, and;
- (vi) Formulate and implement emergency plans and procedures.

### **3.2.1 Biological Safety Officers (BSO)**

Clearly, all the duties to be performed by the employer will require the delegation of responsibilities to other employees in management positions and the employer(s) shall be required to appoint competent persons to assist them in meeting the requirements of their statutory obligations. While it is the BSO who is appointed to undertake some of the statutory obligations of the employer detailed above, the appointment of the BSO will generally depend on the organization and the selected method of meeting its statutory duties. Irrespective of the nomenclature used, the competent person so appointed must have sufficient academic training/knowledge and experience to enable him assist in the implementation of the statutory measures.

Where a BSO is appointed as the competent authority to implement the statutory requirements of the employer, he must be allocated with sufficient time and resources to effectively perform his duties. In addition to advising on the containment and training aspects of the work, the BSO will be expected to provide advice on risk assessment and coordinate the notification procedures. In large organizations, it will be impossible for one person to undertake this role in

addition to other duties such as research and teaching. In the performance of his duties of assisting in the provision of advice and assistance in meeting the organization's statutory requirements, the BSO is expected to undertake the following:

- (i) ensure that local organizational rules are developed and followed for the safety of personnel and people who may come in contact with containment activities;
- (ii) undertake training of personnel in appropriate microbiological practice. The level of training to be provided will depend on the work to be undertaken;
- (iii) undertake investigation of accidents, spillages etc. in the containment facility and implement corrective actions that may be required;
- (iv) ensure the safe storage of modified organisms which are harmful and all other potentially harmful materials are properly kept and also ensure that proper records of these are maintained;
- (v) supervise the appropriate transportation of all modified organisms to other containment facilities or for safe disposal;
- (vi) ensure that laboratories or containment facilities are properly disinfected at the end of each experiment, and/or in case of spillage and before allowing maintenance personnel into the facility;
- (vii) as part of the facility based inspection team's work schedule, participate in all locally organized inspection activities;
- (viii) ensure the regular testing of control measures and equipments for the safety of personnel;
- (ix) ensure that appropriate waste disposal procedures are strictly observed particularly when handling waste material suspected of being contaminated;
- (x) provide technical support to the Genetic Modification Safety Committee on risk assessment and ensure that all statutory notifications are made to the GNBSA, and;
- (xi) constantly provide employees with information relating to changes to the control measures and regulations and ensure that adequate physical security is provided for the laboratory or containment facility.

The duties and responsibility of the BSO are numerous and important for both the organization and people who may come in contact with the work to be undertaken in the containment facility. Where the BSO is not able to perform all the duties described above, other suitably qualified persons may be appointed to ensure that the working environment is safe and the organization can effectively meet its statutory obligations. The use of professionally competent external contractors in performing certain duties is permissible.

### **3.2.2 Training and Supervision**

The principle of **Good Microbiological Practice and Good Occupational Safety and Hygiene** requires the training of personnel and the nature and level of training may be categorized as follows:

- (i) training on recruitment which should include areas such as good microbiological practice and familiarization with local organizational rules and procedures must be undertaken before commencement of work;
- (ii) when significant changes are made in the work activity/ environment or changes are made in the type of equipments to be used, personnel will need to be retrained;
- (iii) the BSO must conduct refresher training programs in order to ensure the maintenance of work standards, and;
- (iv) undertake training of personnel on risk assessment procedures.

It should be understood that the level of training to be provided should be commensurate with the perceived level of risk and the complexity of the operations to be undertaken. Depending on the size of the organization and the level of work to be performed, training may be tailored to meet the needs of individuals, small and large groups. Workers should only be allowed to perform work activities in containment facilities without constant supervision when management is satisfied that the required proficiency of the employee is attained. More formal approaches to training should however be undertaken for higher levels of containment such as containment level 3 activities.

### **3.2.3 Genetic Modification Safety Committees (GMSC)**

The CUR places statutory requirements on individuals and organizations carrying out GM work to establish GMSC to advise management on the associated risk. While the statutory requirement is designed mainly for the provision of advice on the risk assessment to be undertaken, GMSC can also be useful in ensuring that good microbiological practice is maintained and there exist a forum for full and useful discussion involving all categories of personnel involved with GM work. GMSC will also be useful in ensuring that appropriate training is provided to employees and good laboratory discipline is maintained at all times. GMSC are often involved in the formulation of local organizational rules, whose design can include the prevention and/or minimization of accidents.

While there are no hard and fast rules governing the composition of GMSCs, they should ideally consist of both management and employees that have access to the containment facilities and they should consist of persons with sufficient depth, range of knowledge and experience to:

- (i) adequately comprehend the risks to both human health and environment which may arise from the range of activities undertaken at the containment facility and determine the extent to which any risks are uncertain;
- (ii) judge the adequacy of the risk assessment made, and;
- (iii) discuss its findings at committee level to ensure that the advice provided does not represent the views of an individual.

Emphasis should be placed on establishing a balanced committee which represents the views of both management and the employees and ensuring that the committee is managed in such a

way that the views of all its members are heard. The actual composition of GMSC will to a large extent depend on the local environment and the nature of work to be undertaken in the containment facility. The following persons should be considered for membership of GMSC:

- a chairman to be elected by the membership of GMSC;
- management representatives involved in genetic modification activities;
- representatives selected by and from all persons having access to genetic modification facilities or persons who might be exposed to genetic modification work (technical and ancillary staff, students or visiting workers);
- Biological Safety Officer;
- Liaison officer between GMSC and the main safety committee, and;
- Co-opted members to supplement internal expertise specialized in areas such as viral vectors, medical or environmental matters.

The establishment and membership of GMSCs should be provided to the relevant authorities as part of the notification of first use of the containment facility for genetic modification. Any subsequent changes in the membership and composition of the committee must also be provided as and when they occur.

The requirement for the establishment of a GMSC under the contained use regulations does not affect the rights of safety representatives appointed under safety committee regulations to request their employer to establish a safety committee. Such safety committees have the role of maintaining health and safety measures under constant review. For ease of work and in order to ensure a smooth working relationship, it is important that the relationship between such committees and GMSC be clearly defined. In fact, the GMSC should be a sub-committee of the main safety committee usually established in all containment facilities.

### **3.2.4 Health Surveillance**

The CUR does not include a specific requirement for health surveillance for GM work. In developing the health surveillance requirements within the context of the contained use regulations, GMSC should decide whether the genetic modification aspects of the work involves a significant risk to human health and determine the appropriateness of health surveillance measures. The driving force should be the **Accepted Code of Practice (ACOP)** obligation of the employer designed to ensure that all employees working within contained facilities are provided with sufficient health surveillance measures focusing on the health and safety as identified by the risk assessment. The control of substances hazardous to health regulations should require health surveillance for employees exposed to substances hazardous to health which includes biological agents such as GMMs. It will be appropriate to implement health surveillance measures based on the following:

- (i) An identifiable health effect may be associated to the exposure of the employee to substances or biological agents hazardous to human health;
- (ii) There is reasonable likelihood that employees can contract disease as a result of exposure or other negative effects may occur under work conditions, and;

- (iii) Valid techniques are available for detecting indications of disease or other negative health effects.

Health surveillance may also be useful in (i) the evaluation of the measures taken to control exposure to substances hazardous to health, (ii) evaluation of data to evaluate the hazards to health and (iii) determining the level of immunity of workers to biological agents.

### 3.2.5 Low Risk Work Activities with GMOs

Work activities involving level 1 and 2 GMMs with no identifiable risk to human health (such as plant pathogens) will not likely require the implementation of health surveillance measures. Despite the low risk to human health, it will be advantageous to identify workers who may be at greater risk than others because of an underlying medical condition of the employee. The GMSC and management will determine whether an underlying medical condition of its employee(s) would require additional control measures to protect the worker's health. Like all other areas of microbiological risk, other general considerations which might be useful in determining whether additional control measures are required include:

- (i) The existence of historic medical conditions of the employee such as **asthma** which might have been problematic and can be aggravated by exposure to GMMs;
- (ii) The particular employee has medical disorder of the skin, respiratory tract and/or alimentary canal which are sufficient evidence of defective barriers to infection;
- (iii) The level of immune competence of the employee, and;
- (iv) Employees undertaking antibiotic treatment, the therapeutic use of steroids and some forms of self medication which could influence the chance of infection.

### 3.2.6 Higher Risk Work With GMOs

In situations where employees are required to work with higher risk GMMs and it is determined that there exist real risk of ill health resulting from work exposure and methods are available to detect disease, some form of health surveillance will definitely be necessary. Possible hazards related to GMM work include the following:

- (i) GMMs derived from biological agents where modified viruses may exhibit different tissue tropism or the biological agent is less susceptible to therapeutic agents and/or where immunized workers may not be fully protected;
- (ii) The performance of GM work relating to Cloning of oncogenic, tumorigenic sequences, mutant tumor suppressor genes or anti-sense constructs for tumor suppressor genes;
- (iii) Work related with modified prion protein genes;
- (iv) Work with organisms expressing biologically active molecules such as enzymes, hormones and toxins that are likely to present risks to health;
- (v) Exposure to cloned genes which may lead to an immune response and subsequent auto-immune type of disease, and;

- (vi) Work that may cause respiratory disorders especially large scale GMM work activities and the possibility that fusion proteins or inclusions may enhance the disorders.

### **3.2.7 Health Surveillance Procedures**

The following health surveillance procedures are proposed and their application to GM work should be decided based on the existing circumstances. Potential users of the proposed health surveillance measures should take cognizance of the considerations detailed under **higher risk work with GMOs**. The proposed health surveillance measures include the following:

- (i) Monitoring for the presence of biological agents and monitoring their effects on employees. There are a variety of monitoring procedures which may be relevant for GM work including (a) use of serum samples as a means of determining immunity and the efficacy of vaccination or (b) detect sero-conversion indicating exposure. However, it is important to note that serum samples have only dubious values for detecting disease or adverse health effect where the GMO contains genes that are homologous or identical to normal human genes. Considering the case of oncogenes, there is considerable difficulty in detecting people susceptible to cancer or detecting people with the early stages of the disease.
- (ii) Medical surveillance is one of the several options where health surveillance is required but no specific requirements exist for medical examination of GM workers. While it is not a requirement to appoint a medical officer responsible for the continuous surveillance of the health of workers involved with GM work or for such persons to be ex-officio members of local GMSC, it is obviously a useful mechanism that can be explored.
- (iii) Enquiries about the existence of symptoms which can form part of the examination conducted by a qualified medical practitioners or administering questionnaires to enquire about any symptoms that may be related to exposure to hazardous GMO in the work environment. Providing information about symptoms and encouraging self monitoring and reporting of adverse symptoms can also be effective mechanisms for health surveillance procedures.

### **3.2.8 Maintenance of Records of Exposure**

Based on the accepted code of practice, it is important that records of exposure are kept for work with certain biological agents. Records of exposure to hazard group 3 and 4 will require the maintenance of records for at least a 10 year period after work ceases and in cases of delay in detecting ill health, the records need to be stored for 40 years. Biological agents requiring 40 year periods of storage include hepatitis B, C, D and other unclassified hepatitis viruses and human papilloma viruses. Unless the risk assessment for the GMO and the intended work practices indicate that it is not necessary to maintain records of exposure for longer periods, it is also recommended that such records of persons exposed to prion protein genes are maintained for 40 years.

The general consideration relating to oncogenic sequences is regarded as being applicable to all known and potentially oncogenic DNA sequences. Potentially oncogenic sequences handled as preparations of naked DNA or in viral vectors with a human host range may be carcinogens and may be subject to special health surveillance. Unless it is so stipulated by the risk assessment that the exposure is not significant, the collection, maintenance and review of health records of workers exposed to oncogenic sequences will always be required due to the long term nature of the postulated risk from exposure. Health records for such work as a minimum should include exposure to naked DNA in a bacterial host system or in a eukaryotic virus with a human host range. It is prudent to adopt a precautionary approach to work with potentially oncogenic sequences irrespective of whether they are carcinogens or not. Specific consideration should also be given to any historical record of occupational exposure which should necessarily include details of the work and the oncogenes studied, the room number or identification of the laboratories in which work was performed and the dates work commenced and terminated. Such records should be updated periodically, maintained and securely stored for 40 years after termination of work. The employee should be provided with all such records upon cessation of work and the employee must ensure that such records are provided to the next employer to be maintained as part of their records. This is an important health surveillance mechanism for researchers who undertake a number of short-term contracts.

### **3.3 Risk Assessment of Genetically Modified Organisms**

Primarily, risk assessments are undertaken to identify any possible problems emanating from GMO and GMO related work activities. It is obligatory for a thorough and critical scrutiny be carried out by and at the expense of the people or organizations intending to undertake GMO work activities in the Gambia. The completed risk assessment form should be submitted to the GNBSA and only after critical examination and acceptance of its contents, followed by the granting of permission should the proposed work with GMO commence. Acceptably, risk assessments can never give 100% assurance that a GMO or a specific procedure is safe. Therefore, if the GNBSA still has doubts after the critical examination of the proposal, then such doubts should be published in all the existing media channels including the Biosafety website and the proposal subsequently rejected.

#### **3.3.1 Risk Assessment under Contained Use Micro-organisms**

Containment facilities that are proposed to be used for first time for genetic modification activities and before each new GM work is started, an assessment must be made of the risk of the containment facility to human health and safety and, the environment.

Risk assessment may be considered in three ways (i) a suitable and sufficient risk assessment which is required for all activities (ii) a summary of risk assessment required with types of notifications and (iii) a record of the risk assessment which needs to be stored for a period of 10 years after the activity ceases. The risk assessment is all that needs to be considered in order to determine the hazards of the organism, the likelihood that they will actually cause harm and the control measures that are required.

In general, the risk assessment to be undertaken should contain the following elements:

- (i) undertake an identification of potential hazard;
- (ii) assess the potential exposure of the employee to the hazard and determine the consequences of that exposure;
- (iii) undertake an assessment of the level of the risk through consideration of the magnitude of the harmful consequences and likelihood of their being realized, and;
- (iv) select and assign appropriate control measures based on the risk management strategies.

The nature and extent of the details to be considered in a risk assessment will depend on the circumstances. The risk assessment should be suitable and adequate but not necessarily very detailed. The risk assessment can be short in cases where it is obvious that the risks are low or that the proposed control measures are clearly adequate. For instance, simple operations involving low hazards that are well known and well understood, it may be possible to declare the results of such assessments almost at first glance. Complex operations involving dangerous organisms with significant uncertainty on the other hand, will require extensive assessments and may require the acquisition of new data/information. In many instances it is always permissible to assume a worst case scenario and act accordingly. For example, if there is reasonable doubt relating to a range of risk for a given organism, the assessors may simply choose to apply control measures appropriate to the upper boundary. It also necessary to review risk assessments if there is any reason to suspect that the initial assessment is no longer valid due to a significant change in the activity. Such changes might include alteration in the type of operation, the scale of the operation, the containment measures, waste disposal mechanisms or the availability of additional information concerning the GMO.

### **3.3.2 Risk Assessment Parameters**

In general, it will be necessary to record briefly any relevant information since this will be expanded when an assessment of the level of human and environmental risk is undertaken (see more details under **risk assessment for GMMs**). However, all components of the GMMs should be considered including the host organism, the donor(s) from which the inserted DNA has been derived, the inserted gene and any other vector sequences. In most cases, the characteristics of the host organism will be more relevant to a risk assessment than those of the donor organism.

As a general rule, if a donor organism is simply used as a source of well characterized DNA for a selectable phenotype, or a promoter or other control sequence, the characteristic of the donor need not be considered. However, if the insert contains genes encoding biologically active molecules, toxins or virulence factors, then the relevant information from the donor organism should be considered.

### **3.3.3 Risk Assessment for Environmental Protection**

For the majority of scientists and organizations alike, containment measures which are deemed sufficient to protect human health will be adequate to protect the environment. Notwithstanding this general understanding, environmental risk assessments are required to ensure that the containment facility described as sufficient to safeguard human health and safety, is usually adequate to ensure environmental safety at least to a certain limit. Following the undertaking of an environmental assessment, if the level of containment set for human health and safety is judged not to be sufficient, the best approach is to identify which element of the containment is lacking. For instance, an unusual situation might occur where a GNBSA level 2 offered sufficient containment in all but one aspect (e.g. treatment of exhaust gases). The addition of this one facet of control would be deemed sufficient for environmental protection and therefore a GNBSA containment level 3 will not be necessary. Similarly, if insect spread of the GMM were identified as a hazard, the installation of a specific insect control device to trap and kill any flying insect before they enter the laboratory might be a sufficient control measure to protect the environment.

### **3.3.4 “Harm” to the Environment and “Risk”**

While **“harm to the environment”** is difficult to define or quantify but for the purpose of the Gambia Biosafety Framework (BSF) document we define the term as follows:

**“harm means harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part of and in the case of human, includes offence caused to any of his senses or harm to his property”**

For example, following an escape of pollen grain from containment or escape of transgenic animals, the unintentional transfer of genes to a farmer’s crop or livestock is a potential hazard and could constitute harm if realized. Toxic or allergenic effects arising from the expression of genes in pollen is another potential hazard.

From this perspective, the environment is defined as **land, air or water** and would result in harm if an organism affected any or all these components of the environment directly or in such manner that in turn deleterious effects were produced on other organisms (knock-on effect). Components of the environment are here defined as organisms and systems of which these form part-off.

Risk is defined as the probability that a particular adverse event or harm occurs during a stated period of time or results from a particular challenge. In the context of the contained use of GMOs, therefore, the objective of an environment risk assessment is to determine the probability of harm to the environment arising from the escape of organisms from the containment facility. The risk assessment must include escape to the environment by means of waste streams, waste disposal etc. Risk evaluation has to take into consideration an assessment of the degree of potential harm, and the likelihood or frequency of the harm occurring. It is therefore necessary to carry out an environmental risk assessment for work with micro-organisms and transgenic animals or plants.

Finally, the full risk assessment should be submitted with notifications of level B 2 (high risk) GMMs for large scale operations. The logic of the arguments contained in the risk assessment should be clear and detailed enough to avoid the need to request for additional information. Delays emanating from the additional information will not be counted as part of the set period for review of a notification and in addition, it should be understood that work will not commence without the necessary approval of the GNBSA.

### **3.4 Risk Assessment of Genetically Modified Micro-organisms other than Eukaryotic Viruses**

The risk assessment for GMMs other than eukaryotic viruses is intended to provide guidance on risk assessment for human and environmental safety pertaining to work related to modified bacteria, fungi and cell cultures. It will cover most types of cloned DNA including oncogenes, pro-viral DNA and prion proteins. This section is an expansion of the risk assessment parameters and will be useful in the finalization of the risk assessment document.

#### **3.4.1 Structure of Guidance**

The following procedures for risk assessment and the assignment of containment and control measures are recommended:

- (i) Consideration should be given to the predicted properties of the GMMs or the actual GMM to determine if there are any potential mechanisms that could represent hazard to human health;
- (ii) Assign general controls necessary to prevent harm and thereby safeguard human health such as allocating provisional level of containment;
- (iii) Determine the nature of work to be undertaken;
- (iv) Identify potential hazards to the environment and assign any additional containment measures designed to protect other organisms and the environment, and;
- (v) Classify GMMs into two groups: (a) **Group 1:** GMMs not likely to cause harm to humans or the environment and (b) **Group 2:** GMMs that may or will definitely cause harm to humans or the environment.

A variation to the above structure will be in situations where the terms “**access**”, “**expression**” and “**damage**” are used as a basis for the identification of hazard. In such cases, the application of this system of hazard identification will replace (i) – (iii) above. This scheme is used elsewhere and was used to ensure the protection of human health and safety. This method which was in use since the early 1970s was entirely based on cloning type activities. Essentially, it presents a method of determining whether a host strain might be hazardous as a result of the introduction of a foreign gene. The scheme considers three parameters:

- **Access-** the likelihood that the organism could enter and survive in the human body;
- **Expression-** a measure of the level of expression of the cloned protein, and;

- **Damage-** the potential for the expressed protein to cause harm.

The considerations of **access, expression and damage** do not constitute a comprehensive risk assessment. They only give an indication of the level of containment appropriate for human health. There are many instances when consideration of “**access**”, “**expression**” and “**damage**” do not provide reliable indication of the appropriate level of containment desired. The examples include the following:

- (i) The cloning of genes that alter or exacerbate existing pathogenic traits e.g. pathogenicity determinants or antibiotic resistance genes, the dissemination of which might prejudice the clinical use of the antibiotic;
- (ii) Work with host stains where there is uncertainty over the level of attenuation, and;
- (iii) Work that those not involve a construct formed in a classical way from a plasmid vector and an inserted coding sequence e.g. deletion mutants, certain cell fusions etc.

In these cases, containment is better assigned on basis of a full assessment of the GMM rather than the indicative level obtained through the use of access, expression and damage. Much of the guidance in this part deals with activities where there exist some degree of uncertainty and therefore a more in-depth assessment is necessary. The level of detail for individual cases will be different depending on the nature of the hazard or the level of scientific uncertainty. Once a potential harm is identified, a more detailed assessment of the risks associated with the activity should be undertaken. Therefore, appropriate containment and control measures must be assigned on the basis of both human health and environmental considerations of the risk assessment. In most cases, the containment and control measures appropriate for the protection of human health and safety will also be adequate for the protection of the environment. This will be particularly so for work activities involving well characterized mammalian cell lines which are extremely unlikely to pose any risk to the environment.

### **3.4.2 Risk Assessment for Human Health**

In undertaking risk assessment for human health, due consideration should be given to the properties of the GMM to determine the existence of potential mechanisms through which such properties could represent a hazard to human health. The pathogenicity, the biological activity or toxicity of the foreign gene and the mobility of plasmid or viral vectors are factors that should be considered during hazard identification. The factors to be considered include the following:

- (i) **Hazards associated with the host/recipient:** In the process of determining risk to human health, due consideration should be given to the pathogenicity of the host strain including virulence, infectivity and the ability of the GMM to produce toxins. The existence of any harmful adventitious agents will need to be considered, particularly when using cell cultures. It should be noted that a great amount of work is undertaken using tissue in cell cultures and therefore considerable amount of experience is available. Cell lines are often difficult to grow and require specialized defined media

and growth conditions. Once a cell line has been immortalized by an oncogene, it is considered to pose minimal risk of oncogenicity (induction of tumor). Well characterized cell lines with a history of safe use, pose little risk to both the employee and the environment.

- (ii) **Hazards arising directly from inserted genes** are mainly concerned with cases where the product of the inserted gene has biological properties which may cause harm (such as toxins, allergens, hormones etc.). In cases where the inserted gene is not expressed or the expressed product is produced in an inactive form such as in an insoluble inclusion body, it is unlikely that the gene product will cause harm to human health.
- (iii) **Hazards arising from the alteration of existing pathogenic traits:** Many GMM modifications do not involve genes whose products are inherently harmful but adverse effects may arise as a result of exacerbation or alteration of existing pathogenic traits. This may occur as result of the product of inserted gene acting along side existing pathogenic determinants. Alternatively, it is possible that modification of normal genes may also alter pathogenicity. The following issues should be considered when identifying GMM related hazards:
  - (a) The existence of increased infectivity or pathogenicity;
  - (b) The possibility of disabling mutations within the recipient gene due to the insertion of a foreign gene, and;
  - (c) Does the foreign gene encode a pathogenicity determinant from a related organism?
- (iv) **An inserted Gene** that does not produce a harmful phenotype in the recipient micro-organism could cause harm as a result of natural gene transfer to another possibly related organism. Would the wide-spread application of an inserted gene into the environment cause specific harm due to its characteristics, is an issue of concern that needs to be addressed. It is also important to determine if the recipient organism would survive in the environment in the event of a breach of containment and whether the vector is mobilisable. It is known that certain gene strains can survive for up to 7 days in the intestine of animals and for a similar length of time in the environment.

### 3.4.3 Risk Assessment for Environmental Harm

The objective of an environmental risk assessment is to determine the probability of adverse consequences of harm to the environment resulting from the escape of an organism from a containment facility. This assessment should include all possible routes of escape to the environment through waste streams and waste disposal mechanisms. Invariably, harm results if hazards are realized. Therefore it is necessary to identify the actual hazards followed by determining the likelihood of their being realized and the consequences of their realization. This procedure allows for the determination of the existence and magnitude of the risk. The following is a summary of the procedure to adopt in environmental risk assessment:

- (i) identify the hazard;

- (ii) assess the likelihood of the identified hazard being manifested;
- (iii) assess the consequences of the identified hazards being manifested;
- (iv) determine the risk of harm or injury, and;
- (v) management or control of risk.

**(a) Hazard Identification**

In the hazard identification process, considerations of the following issues are important:

- the capacity of the GMMs to survive, establish disseminate and/or displace other organisms;
- pathogenicity to animals and plants;
- potential for transfer of genetic material between the GMO and other organisms;
- products of the gene expression especially if they are toxic;
- other negative effects on organisms, and;
- phenotypic and genetic stability.

In considering the hazards emanating from the release of GMMs to the environment, consideration should be given to the possibility of the existence of any of the characteristics mentioned above bearing in mind the biological characteristics of the recipient or host organism, the insert and the GM in question. The capacity of the GM to survive, establish and disseminate itself is an important phenomenon that should always be considered.

If an organism is not capable of surviving in the environment, as may be the case in most of the multiply disabled organisms used in containment, none of the other hazard factors are likely to manifest themselves and the organism, in general can be regarded as being safe. Alternatively, if the organism has the ability to survive, establish and possibly disseminate itself in the environment, the other types of hazards should be carefully considered. In considering the ability of the organism to survive in the environment, it should be remembered that the environment in this circumstance is by extension including survival in the guts of animals and all types of association with the living organisms, as well as living in soil and water. However, even if an organism has limited capacity to survive, it will be important to determine the potential of the gene product's ability to persist in the environment and eventually cause harm or passively transfer the gene to other organisms in which it may be expressed. This situation is likely to occur if large numbers of GMMs are envisaged to escape through waste streams and other outlets.

**3.4.4 Assessment of Likelihood**

A key factor in assessing the likelihood (probability and frequency) of the hazard occurring is to determine the potential of the environment in which the GM activity is being undertaken and this includes the wider and local environment. It is important to consider the potential exposure of the living and non-living environment to GMMs and the magnitude and duration of such exposure. Specific characteristics (such as climatic conditions, geographic locations, soil conditions and the existing fauna and flora) that could contribute to the manifestation of the

hazard should be assessed. It should be understood that a plant pest which exists in temperate regions, may not be a pest in the tropics where the climatic conditions are different.

In the process of estimating probabilities and frequencies, the number of organisms that might escape despite the control measures instituted should be considered. The probability of the hazard being realized will often depend on the number organisms which might escape. The likelihood of the organisms to escape should be expressed as **“high”**, **“Medium”**, **“low”** or **“negligible”**.

### **3.4.5 Assessment of Consequence**

Upon completion of the likelihood assessment, the consequences of each hazard should be estimated. Like the conditions prevailing under likelihood, the consequences will depend to a large extent on the environment (both locally and in the wider context). The consequences of the hazards of the gene in the environment can be described as **“severe”**, **“medium”**, **“low”** or **“negligible”**. If the assessment of the potential consequences of a hazard were found to be low or negligible, even if the probability of its occurrence was high, the risk of harm will be low.

The evaluation of magnitude of a potential consequence is difficult and therefore a degree of personal judgment will be necessary. An element of qualitative guideline is provided below:

**The consequence of hazard emanating from a GM from which a bacteriocin gene is released in the environment, the effects of the toxin production on other soil borne micro-organisms might lead to “severe”, “medium”, “low” or “negligible” consequences.**

**Severe** consequences here reflects a major change in the number of one or more species leading to negative effects on the functioning of the ecosystem and/or other ecosystems. For example, the negative effects of the functioning of the ecosystem might be a significant alteration of biomass turnover or the supply of nutrients to crops and such changes will not be easily reversible.

**Negligible** consequence indicates that no measurable change exist in the microbial population affecting the functioning of the environment or ecosystem. This does not connote some fluctuations in indigenous microbial populations as long as this is within the natural range.

### **3.4.6 Determination of Risk**

In the determination of risk, there will be some element of personal judgment that will be needed to assess the individual components of the risk. Like the assessment of the consequence of the hazard, the risk shall be defined as **“high”**, **“medium”**, **“low”** or **“effectively zero”**. The key factor influencing the likelihood of manifestation of the hazard will be the level of containment set during the first part of the risk assessment. Therefore, even if the consequence of the gene transfer or expression was classified as being **“severe”**, the resultant risk might be classified from **“high”** to **“effectively zero”**. In cases where the containment was inadequate, the likelihood of hazards emanating from the containment facility might be **“high”** and the

resultant risk to the environment will be “high” but if the containment measures were adequate, the likelihood of gene transfer to the environment might be “negligible” and the resultant risk to the environment will be “effectively zero”. Since a lot of personal value judgment is involved in determining risk, specific advice on risk assessment and containment levels should be sought from the Biosafety Authority.

### **3.4.7 Risk Management**

Based on the discussion so far, the users of these guidelines need to re-evaluate the adequacy and effectiveness of the containment level and determine their suitability to protect the environment. It is important to realize that “low” or “effectively zero” risks do not require additional control measures. But if risks from a specific hazard exceed these levels, then additional control measures should be instituted in order to reduce risks to “low” or “effectively zero”. For example, if the containment facility was found to be inadequate, posing a risk level of “medium” or above, then additional control measures will be required. Such control measures may consist of effectively controlling the numbers of viable organisms released in the facility’s waste stream. However, it is unlikely that additional control measures over and above those applied for human health and safety would be required for the environment.

### **3.4.8 GM Classifications**

GM classification into group I and II is part of the overall risk assessment criteria. The criteria require that **Group I** GMMs are unlikely to cause disease to humans, animals or plants and are unlikely to be harmful to the environment. Micro-organisms not fulfilling these criteria will be classified as **Group II**. It is important to note that an organism can be classified as Group II GMM on environmental grounds alone, irrespective of the “low” or “effectively zero” hazard it may pose to humans. For example, a plant pathogen may be of no risk to humans but should be classified as **Group II** on condition that it is capable of causing harm to indigenous plants or the environment.

It is important to understand that the classification of a GMM into Group I or II and determining the correct level of containment, though related, are actually separate procedures. Notwithstanding the procedures/guidance detailed above, an assessed containment level 1 together with the observance of the **Principles of Good Occupational Safety and Hygiene** will generally be adequate for Group 1 GMMs. However, if a GMM is classified into Group 1 and the assessed level of containment is above level 1, then both GMM classification and the level of containment assigned should be re-checked to ensure that the classification are correct. Though the GMM classification and assigned containment level could be correct, as a precautionary measure it is better to re-check. It is important to note that assignment to a particular containment level does not in any way determine the classification of a GMM.

## **3.5 Risk Assessment of GM Modified Human and Animal Viruses and Viral Vectors**

This part of the guidelines is designed to provide guidance on the risk assessment for GM work related to human and animal viruses and vectors. The guidelines are supplementary to the general guidance provided in the first part of the regulations. For the purpose of these guidelines, the term **animal** shall be taken in its broadest sense to include vertebrates and invertebrates. Due to the sensitivity of the high risks associated with GMM human and animal viruses and viral vectors, it is obligatory for a thorough and critical scrutiny be carried out for work activities under this schedule.

**Gene therapy** using viral vectors requires rigorous control of the production and safety testing methods of the technology prior to the use of the technology on human subjects. In addition to the approval provided by the GNBSA, approval should also be sought from the Medicines Board of the Department of State for Health and Social Welfare.

### 3.5.1 Structure of the Guidance

The following procedure for risk assessment, the assignment of containment levels and control measures are recommended for risk assessment of GM human and animal viruses and viral vectors:

- (i) re-examine the predicted properties of the genetically modified virus to determine if there are any potential mechanisms through which the GM could present a hazard to human health;
- (ii) also evaluate the likelihood that the GM virus could actually cause harm to human health;
- (iii) assign adequate levels of general control measures necessary to safeguard human health such as allocation of provisional level of containment;
- (iv) consider the nature of work to be undertaken and assign additional control measures if required;
- (v) identify potential hazards to the environment, especially for non-domesticated animal species and based on the assumption that the control measures necessary to safeguard human health have been applied, assign additional containment measures to protect the environment, and;
- (vi) classify the GM human and animal viruses and viral vectors into **Group 1 or 2** categories.

It is appropriate to understand that the system of hazard identification for GMMs other than **Eukaryotic Viruses** outlined in other parts of these guidelines utilizing terminologies such as **access, expression and damage** cannot be used for viral vectors.

### 3.5.2 Hazard Associated With the Vector

It is important to take particular care in the assessment of viral vectors that have the actual or potential ability to infect human or human cells. Within the provisions of the 1994 **Control of substances hazardous to health (UK)** all biological agents (including all viruses and viral vectors) that may cause infection, allergy, toxicity or any other infection to human health

should be classified into hazard groups (**categorization of biological agents according hazard and categories of containment**) to be developed by the Department of State for Health and Social Welfare.

### **3.5.3 Viral Vectors with Reduced Pathogenicity**

For genetic modification work which involves viruses that have a human host, it is recommended to use disabled or attenuated viral vectors with reduced pathogenicity. The use of viral vectors without a human host range should be used where appropriate. The origin and mechanism of such attenuation (reduced strain of viral vector) must be well understood and should form an important part of the overall risk assessment. In the process of determining whether a viral vector is adequately disabled, the possibility of reversion or complementation should be considered and it should also be confirmed that the virus is disabled after modification. The likelihood of reversion will to a large extent depend on the mechanism used in the attenuation process. For instance, deletion mutants are less likely to revert to wild types than point mutations or conditional lethal mutants.

In cases where a viral vector is an attenuated or disabled derivative of a human pathogen, it may be necessary to re-classify the vector into an alternative hazard group for the purpose of determining the appropriate containment level. Further detailed and specific information on disabled vectors will be provided by the Department of State for Health and Social Welfare and if doubts exist on the correct biological agent hazard group for an attenuated or disabled virus, it is advised that GNBSA be contacted for further discussion.

Experiments involving viral vectors that do not normally infect human cells in culture and for which there is no evidence of human infection are generally considered to represent minimal risk to the operator and GNBSA containment level 1 is adequate to protect human health except in cases where the expression of allergenic or toxic proteins may occur. Despite this provision, a higher containment level may be required to control risks to other species. These provisions do not involve the packaging of cell lines intended to produce mature infectious virus particles. In the process of determining whether infectious virus may be produced, particular attention should be paid to the circumstances in which an endogenous or latent virus could act as a **helper** sequence.

### **3.5.4 Hazards Arising From an Inserted Gene Product**

It should be understood that the addition of nucleic acid sequences into viral vectors can result in potential adverse effects to human health and safety. For instance, the addition of nucleic acid sequences into a viral vector may result from the direct effects of an expressed gene or as a sequence of an alteration in the overall properties of the GMM. Attention should be given to the level of expression and the site of insertion to determine the existence of known or suspected pharmacological or physiological effects including the possibility of other effects beyond those sought in the GMM construction. For example, a non-harmful human protein expressed in vaccinia virus may induce **auto-immune** disease if an operator accidentally gets infected. Particular attention should be given to the insertion of genes which are likely to alter the growth, replication or differentiation of cells into viruses capable of infecting human cells.

Work with modified viruses may result in serious consequences for people who are occupationally infected or exposed and it is necessary that additional containment and control measures over and above those required for viral vectors will be required. These must be determined and applied at the correct level following a detailed risk assessment.

### 3.5.5 Genes Associated With Tumor Development (Oncogenes)

Genes associated with the generation of tumors in humans and other animals could form the basis for defining **Oncogenes** but several other genes generate phenotypes in cultured cells that may suggest that they may be associated with tumorigenesis.

The formation of **cancer** requires the activation (either by mutation or over expression) of oncogenes and the activation through mutation or deletion of tumor suppressor genes. It usually involves a multi-step process which involves the activation or inactivation of several genes with their cells becoming more tumorigenic as genetic changes occur over time. Although some experimental systems show that the introduction of one change into a small number of cells can cause cancer, it is generally accepted that cancer will not occur in such cases. Notwithstanding the results of the experiments, as a general rule, if the gene is stably introduced into a stem cell, such cells and their progeny could be one step closer to forming cancer. Such potentially serious outcomes should not be dismissed lightly.

### 3.5.6 Hazards Arising From the Alteration of Existing Pathogenic Traits

Significant modifications to eukaryotic viral vectors do not usually involve genes whose products are inherently harmful but adverse effects may nevertheless arise as a result of exacerbation or alteration of existing pathogenic traits. This is likely to be the end product of inserted genes acting along side existing pathogenic determinants. On the other hand, it is possible that modification of normal viral genes may also alter pathogenicity. In identifying potential hazards associated with the modification of a virus, the following major questions should be considered:

- (i) **Alteration of tissue tropism or host range:** The possibility of the structure of the receptor binding site will be altered or will the product of the inserted gene be incorporated on the surface of the virus with the possibility of forming a **novel** receptor binding capacity should be determined. It should be noted that cell or tissue tropism may also be affected by alterations in the transcriptional control of viral genes.
- (ii) **Increase in infectivity or pathogenicity:** The questions that need to be answered include (a) could the modified virus show an altered susceptibility to host defense mechanisms and (b) is the recombinant likely to have enhanced effects upon an immune-compromised host, beyond those normally expected with the parent virus?
- (iii) **Recombination or Complementation:** Will disabled or attenuated viral vectors be overcome by recombination or complementation through (a) accidental

- infection of a laboratory technician or (b) accidental cross contamination of cultures in the laboratory?
- (iv) **Availability of prophylaxis or therapy:** Will viral susceptibility to anti-viral drugs be affected by genetic modification or can vaccination or normal immune status be expected to protect against the modified virus?

These are all important questions that need to be answered in identifying potential hazards associated with the modification of eukaryotic virus which may show adverse effects as a result of exacerbation or alteration of existing pathogenic traits.

### **3.5.7 Deliberate Alteration of Tissue Tropism or Specificity**

There is increasing interest in the modification of virus tropism for scientific or therapeutic reasons and this is usually carried out by modifying the receptor binding proteins. Due to the current understanding of viral pathogenesis, the consequences of changes in tropism are difficult to predict. The modification techniques for tissue tropism are in their infancy stages but the potential of their rapid development are evident. Therefore, risk assessments involving modification of tissue tropism must consider the possibility of the manipulating process to result in success.

Generally, in conducting experiments designed to generate the replication of tissue tropism, competent viruses with novel tropism or other novel characteristics will require higher levels of containment subject to the determination of the biological characteristics of the recombinant. During the risk assessment, the following questions should be considered:

- (i) Is it possible to alter the route of transmission of the modified virus, and;
- (ii) What are the predicted effects of the modified virus in tissues not normally infected by the virus?

### **3.5.8 Likelihood of GM Virus Actually Causing Harm to Human Health**

The initial stage of the risk assessment process that is outlined above involves identifying those features of the GMM which have the potential to cause harm to human health. It is recognized that in some instances, it is possible to draw theoretical scenarios to suggest that a particular modified virus may be hazardous to human health but to categorically indicate that the likelihood of these scenarios occurring is becoming relatively insignificant. Factors that may be considered as likelihood include analysis of the probability that rare events such as mutations that take control of disabling mutations may occur and a judgment as to the fitness of the modified virus. Issues relating to likelihood of harm arising will be difficult to handle in situations where no firm data exist to make informed judgment. A great deal of caution must therefore be applied when discounting on the basis of likelihood of those predicted properties of the modified virus identified above (hazards associated with the vector, viral vectors with reduced pathogenicity, hazards arising from the inserted gene product and hazards arising from the alteration of existing pathogenic traits).

### 3.5.9 Likelihood of Rare Events Occurring

In cases where there is reliable data available, it is possible to assign precise or estimated frequencies to an event and this is possible in the case of recombination and reversion frequencies which may lead to the production of competent viruses. However, in other cases, it may be possible to adopt a descriptive assessment of the probability of the estimated frequency to an event based on experience in working with a specific virus or other comparable viruses or with specific working methods.

The judgment surrounding the assessment of likelihood can best be illustrated by considering a harmful gene cloned into a vector containing a single disabling mutation. If inserted at a separate location from the disabling mutation homologous recombination could produce a replication of the competent virus carrying the harmful gene. This situation is possible through cross contamination with the wild type virus in the laboratory, recombination with viral sequences in the packaging cell line or from a person already infected with the wild type virus. Such cases will be judged as sufficient to require additional control measures. In order to minimize such cross contamination of this type, the simultaneous handling of wild type viruses and recombinant viruses in the same laboratory should be avoided where possible.

### 3.5.10 General Control Measures to Safeguard Human Health

The assignment of general control measures will involve making judgment as to the overall potential hazard of the recombinant virus identified under the following sections above: (i) **the determination of the predicted properties of GM virus representing a hazard to human health** and (ii) **the likelihood that the GM virus could actually cause harm to human health**. In assigning general control measures, it should be understood that the potential to cause harm might involve a combination of factors identified within different aspects of the hazard identification process. For instance, a disabling mutation in a viral vector which depicts a high frequency may not appear to be significant if the wild-type is only a weak pathogen. However, the high reversion frequency could have adverse consequences if the vector was used to clone toxins or oncogenes which inadvertently will require additional containment and control measures.

The first step in assigning control measures is to determine the suitability of the recombinant virus for work in one of the four containment levels which invariably will correspond to the parent virus on condition that it is a human pathogen. Where it is predicted that the modified virus will be considerably more hazardous than the parent virus, it may be appropriate to assign it to a higher containment level. This should be followed by a determination of the adequacy of the minimum requirements for the selected containment level or whether additional containment measures need to be applied. Importantly, it is possible to identify and improve particular aspects of the experimental design or work procedures in order to minimize risk to human health and safety. Management systems such as increased monitoring by internal inspectors, regular training and awareness creation among employees can also be implemented and/or improved upon.

Additional guidance on containment and control measures is provided under **Regulatory Requirements for Determining GMO Containment and Control measures**. However, the underlying principles of containment and control measures for all GMMs are (i) **Good Microbiological Practice** and (ii) **Good Occupational Safety and Hygiene**. It is also wise to recommend the following additional containment and control measures for GM viruses capable of infecting human cells:

- (i) assign and implement measures to prevent cross-contamination during laboratory work designed to minimize the possibility of adverse consequences resulting from recombination or complementation viruses;
- (ii) carry out regular testing design to detect the presence of adventitious agents and replication competent virus, and;
- (iii) in order to minimize risk of accidental self colonization with infected cell lines, avoid infecting cell cultures including those of other employees and family members.

The authority responsible for work activities in the laboratory (supervisor) should ensure that the local rules in the work environment (laboratory) provide sufficient guidance on the maintenance of laboratory discipline and avoid accidental inoculation of employees. In order to ensure that local rules are satisfactorily implemented a program of internal inspection and/or active monitoring by the BSO should be undertaken. All employees should be adequately trained in good laboratory techniques at recruitment and whenever new equipments are purchased or the conditions of work/work materials change. All employees should be fully aware of the potential hazards of the work to be undertaken and work environment itself. Employees as part of their employment requirements should have a working knowledge of the nature and importance of any disabling mutations. Access to the laboratory should be strictly limited to designated workers and only authorized personnel.

### **3.5.11 Consideration of the Nature of Work**

Irrespective of the information provided in the risk assessment and the various precautionary measures taken, an additional element of the risk assessment process includes a review of overall work to determine if the work involves any non-standard operation that may affect risks that are not covered in the general requirements for a specific containment level. Examples of non-standard operations may include the following:

- (i) inoculation of animals with modified virus;
- (ii) the use of equipment likely to generate aerosols, and;
- (iii) the use of high titre virus.

Any such non-standard operations will likely result in risks that are not accounted for in the provisional containment under **general control measures to safeguard human health** and therefore additional containment and control measures need to be applied. For instance if a class 2 cabinet were to be used for work that involves aerosol generating procedures with a virus normally transmitted through an airborne route, special care must be taken to ensure adequate level of employee protection. This scenario will therefore require a more rigorous testing

regime than usual, perhaps involving a six-monthly testing of cabinets and redesign/improvement of the laboratory ventilation systems.

### 3.5.12 Risk Assessment for Environmental Protection

In line with the provisions under the **Contained Use Regulations**, it is relevant to consider the overall risk to the environment. Evidently, the primary consideration for risk assessment of GM human and animal viruses and viral vectors would be a determination of the capability of the virus infecting animals (vertebrates and invertebrates). For the benefit of the user of this guideline, the assessment procedures detailed below do not include GM plant viruses.

If the risk assessment indicates an inability of the virus to infect any other species except humans, this information should be contained in the assessment document accompanied with adequate justifications. In such instances the risk to the environment will be negligible. The risk assessment must consider the potential risk to the environment if the virus has the potential to infect other animal species (both vertebrates and invertebrates). Particular attention should also be paid to viruses that are known to be pathogenic to wildlife.

In assessing the risk to the environment caused by the Genetic Modification of human and animal viruses and viral vectors, the viruses and viral vectors should be assessed for the following:

- (i) **Survivability of the virus and viral vectors:** Do we have any reason to believe that the modification carried out on the virus may result in increased survivability of the virus in the environment. If the virus is capable of surviving in the environment for a long period of time and there exists indigenous species with which it can recombine, then additional consideration should be given to the likelihood of harmful sequences being transferred to closely related viruses and the possibility that selective pressure could lead to the emergence of mutant derivatives that are more harmful than the recombinant virus;
- (ii) **Alteration of Tissue Tropism:** Is the genetic modification of human and animal viruses/viral vectors undertaken likely to alter the tissue tropism or the host range of the recombinant virus;
- (iii) **Increase in Infectivity or Pathogenicity:** Where doubts exist on the extent of the infectivity or pathogenicity of the modified virus, this should be considered in the risk assessment for environmental protection. An additional dimension which should be considered is the likelihood of the modified virus's ability to show altered susceptibility to host defense mechanisms;
- (iv) **Effects on other organisms:** It is necessary to consider the possible effects of the GM virus other than the desired effects. For instance, it is important to determine if the inserted code for a protein with a known or suspected inhibitory, detrimental or physiological characteristics have other possible effects on any other organism;
- (v) **Environmental Release:** It is also important to determine all the possible routes of transmission or escape to the environment of a GM virus. Furthermore, the

- risk assessment should indicate if such routes will allow the GM virus and/or its products to access organisms in which effects may be manifested, and;
- (vi) **Availability of control agents:** Determine if the virus's susceptibility to control agents will be affected by genetic modification. For instance, can vaccination to domestic animals or normal immune status in any animal be expected to protect the animal against the modified virus?

Any hazards identified from the above considerations should be assessed utilizing the approach under **risk assessment of GMMs other than Eukaryotic viruses (2.5)**. The procedure recommended for assessing environmental risk for this category is assessment of the **likelihood, consequence, determination of harm and management of risk**. The possibility of accidental escape of the virus and its survival in the environment are important in assessing the environmental risk. It is re-emphasized that if the virus is to be used at high levels of containment due to the risks to human health and safety, the prescribed containment and control measures will also be sufficient to protect the environment.

Clinical trials may indicate that certain viruses have limited survivability in the environment or is known not to infect Gambian hosts, in such instances, the likelihood that a hazard will be realized in the environment could be considered as "low" or "effectively zero". In considering survival of viruses in the environment, it is important to determine the likely route of entry to the environment. The likelihood of aerosol's survival in the environment may be poor but the virus may survive very well in infected animals. The ability of the virus to infect hosts and replicate within them are also important characteristics to be considered.

It is also important to remember that if a modified virus is assigned to a low level of containment on the basis of its risk to human health and safety but its final risk associated with environmental safety is not considered "negligible", then additional control measures need to be undertaken. It will also require a re-assessment of the risk to the environment. The additional control measures to be implemented should be designed to minimize the likelihood of environmental exposure. Emphasis should be placed on the likely routes of contamination which may include the disposal of infected material designed to minimize the risk of accidental spread of the virus beyond the containment facility. Other viruses, which can be spread through insect vectors or airborne mechanism, may require changes in the ventilation systems provided in the containment facility. The containment level for viruses that are pathogenic to animals should be maintained at a minimum level and may require the further authorization of the Department of State for Agriculture through a licensing process.

### **3.5.13 Classification of GMMs**

As part of the risk assessment, it is necessary to classify GMMs into Group 1 or 2 categories and it determines the notification requirements for the work to be undertaken. The key consideration is to determine the likelihood of the parental organism, the inserted gene or the modified virus causing harm. The risk assessment and the likely decisions about containment levels outlined above will be important in determining the classification groups. As part of the overall guidance, it can safely be assumed that any genetically modified virus requiring

containment level 2, 3 or 4 will likely fall within the Group 2 category. However, border lines cases do exist which are exceptions to this rule. Similarly, GM work, which is assigned to containment level 1, may require classification Group 2 due mainly to environmental concerns.

In cases where the phenotype of the recombinant virus that is under construction may be the major focus of the researcher, some thought must also be given to the possibility that harmful sequences may be transferred to closely related viruses. At this stage, it is important to consider the potential for a disabling mutation in the initially constructed virus to be over come by recombination with the wild type sequence through co-infection of a cell with both the recombinant and the wild type viruses. It may also be as a result of a recombination with viral sequences present in the packaging cell line. In a situation where the repair of a single disabling mutation is reasonably anticipated and it could produce a virus that might be regarded as seriously harmful, it is relevant to classify the virus into Group 2.

Within the context of environmental considerations, a virus that is capable of persisting in the environment and exchanging genetic material with related viruses, the obvious presence of harmful sequences will dictate the classification of such viruses into Group 2. Where doubts exist on the appropriate level of classification or where the vector does not meet all the applicable criteria, the GMM should be classified into Group 2. Further requests to consider its classification into Group 1 should be adequately justified in the notification to the Gambia National Biosafety Authority (GNBSA).

### **3.6 Determining GMO Containment and Control Measures - General Guidelines**

The proposed GMO (Contained Use) regulations shall require specific occupational and environmental safety and containment standards. The level of the containment and control measures required will be commensurate with and determined by the risk assessment undertaken. While a lot has been taken into consideration in the process of developing the **Contained Use Regulations (CUR)** and the subsequent control measures, users of these regulations will need to take into account other existing legislations.

The proposed guidance is divided into two parts for the specific benefit of the user. The first part describes in general the requirements of the CURs and other existing legislation and guidance. The second part provides greater detail for the specific requirements of the CUR which are perceived to be relevant to all future GMO activities in the country. Other subsequent sections detailed below are further designed to give specific guidance on the selection of the appropriate containment and control measures for specific types of GMO and GMO activities in the Gambia:

#### **3.6.1 Contained Use Regulations (CURs) and other Guidance**

It is important to use the following legislation when assigning appropriate containment and control measures:

- (a) Activities which involve genetically modified organisms (GMOs) in contained use must use barriers to minimize their contact with the general population and the environment. In order to re-enforce the physical barriers, biological and/ or chemical barriers can be used as the need arises;
- (b) Containment and control measures to be adopted must be selected based on their appropriateness to the risk of the activity to both human health and the environment. In the specific case of GMMs, it will be necessary to use the **principle of Good Microbiological Practice (GMP) and Good Occupational Safety and Hygiene (GOSH)**. **GMP** and **GOSH** principles will be further discussed in greater detail in another section;
- (c) The Contained Use Regulations require that the risk assessment be utilized to determine the level of containment and it is recommended that this approach be adopted for the Gambia;
- (d) The main elements of any risk assessment for human health and environmental safety should include:
  - (i) identification of potential hazard;
  - (ii) a comprehensive assessment of the level of exposure;
  - (iii) an assessment of the level of risk (this can be determined by considering the magnitude of the harmful consequences and the likelihood of their accidental release), and;
  - (iv) Assessment and selection of appropriate control measures (risk management) including comparison of alternative measures where necessary.

### **3.6.2 Principles of Good Occupational Safety and Hygiene**

The principles of **Good Occupational Safety and Hygiene (GOSH) and Good Microbiological Practice (GMP)** do not involve any physical containment. They however cover work practices and other non-physical methods of control. The GOSH principles are designed:

- (i) To keep the workplace and its environment reasonably free from adverse exposure to physical, chemical and biological agents;
- (ii) To exercise engineering control methods at source and to supplement these with appropriate personal protective clothing and equipment where necessary;
- (iii) To test and maintain control measures and equipment;
- (iv) To test for viable process organizations outside the primary physical containment facility/area where necessary;
- (v) to provide training for personnel at all times, and;
- (vi) to formulate organizational based rules for the safety of personnel.

### **3.6.3 Containment and Control Measures**

It is proposed that the GNBSA recognizes and adopted 4 (four) levels of containment for both large and small scale operations and these include the following:

- (i) GNBSA Containment Levels 1-4 (for small scale); and,
- (ii) GNBSA Containment levels B1-B4 (Large Scale).

Similarly, animal containment facilities are divided into four equivalent levels. The provisions for glass-house/growth room containment conditions are however not divided into specific containment levels. Instead, basic containment levels with a series of additional measures are provided to control specific risks. Where it is proposed to inoculate animals with viable GMMs, animal containment levels corresponding to that used in the laboratory for affected micro-organisms should be used.

The containment measures assigned for the protection of human health will not always provide appropriate protection for the environment. The assignment of measures suitable to protect human health, undertake environmental risk assessment and other additional control measures should be taken where necessary. Risk assessment should be used to identify specific elements of containment which may be lacking and following which containment levels should be adjusted accordingly. Animal scientist, with aid of appropriate literature can obtain additional information on **categorization of biological agents according hazard and categories of containment**.

#### **3.6.4 Preventing and Controlling Exposure**

The primary consideration for GMMs which may affect the health or well being of any organism and are also biological agents should be to prevent of exposure. Where it is not possible to prevent exposure, appropriate measures must be taken to control exposure.

Controlling exposure can be more involving since it includes the development of work processes and engineering control measures designed to avoid or minimize the escape GMMs into the workplace. The used of totally enclosed process and handling systems such as cabinets, enclosed fermenters and exhaust ventilation systems will increase the level of controlling exposure. Other control measures needed include:

- (vii) frequent testing and overhauling of appropriate control measures and equipment;
- (viii) the provision of sufficient general ventilation which may include the use of negative pressure;
- (ix) maintain the barest minimum of workers to be likely exposed to GMM material and containment area;
- (x) unless a responsible member of staff is present, prevent entry for cleaning, servicing of equipment, repairs or other activities outside the normal work of the laboratory. In case of higher containment levels, laboratory surfaces need to be disinfected including fumigation where necessary;

- (xi) within the realm of justifiable reason, minimize the period of exposure for workers to GMMs and work area;
- (xii) the employer should ensure that suitable personal protective clothing and equipment are provided for the use of the employees likely to be exposed to GMMs;
- (xiii) the laboratory procedures developed should provide for the use of hygienic measures compatible with the aim of prevention or the reduction of the accidental transfer or escape of GMMs from the work place;

Other hygienic measures that may be undertaken to increase the control of GMMs exposure include:

- (i) frequent and regular decontamination or disinfection of surfaces, walls, equipments, protective clothing designed to minimize the transfer or escape of GMMs from the workplace;
- (ii) the provision of adequate facilities for washing, changing and storage of clothing including adequate arrangements for laundering contaminated clothing;
- (iii) prohibition of eating, drinking, smoking, storage of food and applying of cosmetics in containment area;
- (iv) provision of adequate means for safe collection, storage, treatment and disposal of waste (including the use of secure and identifiable containers);
- (v) provision of adequate arrangements for the safe handling and transportation of GMOs within the workplace;
- (vi) the development and testing of plans to deal with GMO related accidents;
- (vii) where necessary and technically possible, continuously monitor and test for the presence of GMOs used outside the primary physical containment area;
- (viii) display a biohazard sign and other relevant warning signs, and;
- (ix) make vaccines available where appropriate.

### 3.6.5 Control of Substances hazardous to Health (COSHH)

In the case of Genetically Modified Micro-organisms (GMMs) which are also biological agents (micro-organisms which present a hazard to human health) must also comply with the requirements for classification, risk assessment and control measures as set out in the **Control Substances Hazardous to Health** and the **Accepted Codes of Practice**. Specifically, those GMOs categorized as biological agents in hazards group 2, 3 or 4 must be handled at specified minimum containment levels.

It should be noted that GMMs which are also biological agents, the appropriate minimum of containment level is determined by the hazard group it is assigned to under COSHH and the approved list of biological agents. As an example, hazard group 2 biological agents will require containment level 2 or (B2) as a minimum. Hazard group 3 will require containment level 3 or (B3) etc. It should however be noted that not all GMMs will be defined as biological agents under COSHH. Instead, only those GMMs which present a hazard to human health will be assigned as biological agents. Importantly, COSHH does not consider environmental risk.

Therefore, containment and control measure requirements for a particular organism and in a particular activity may sometimes differ. Where there is a discrepancy the higher containment level should be applied.

### **3.6.6 Management of Health and Safety at Work Regulations**

In principle, **GOTG Civil Service Rules and regulations**, the **Department of Labor and Social Welfare**, the **Workmen's injury and Compensation Act** while providing for an element of health care and limited compensation to workers, the present provisions do not adequately cater for the occupational safety for its employees.

It is the responsibility of employers to appoint competent persons to assist them in developing and ultimately complying with health and safety regulations. While the ultimate responsibility remains with management in the context of work with GMMs, the requirement for competent persons can be satisfied by the appointment of a competent Biological Safety Officer (BSO). Employers should ascertain within the scope of reason, the health safety and welfare of employees at work.

### **3.6.7 Organizational Controls**

All employers in organizations undertaking GMM activities should ensure that local level rules are drawn-up for the safety of all workers. Such organization should clearly spell out management and organizational responsibilities and duties. It is prudent that local **Genetic Modification Safety Committees** are established and members of such committees should be involved in the formulation of organizational based rules. Issues to be covered in the rules will largely depend on the local circumstances and the nature of work to be performed but the following elements may be useful in the development of work rules:

- (i) The selection and training of the workforce (including contracted staff and cleaners) and the subsequent stringent supervision of work;
- (ii) Organizational policy for disinfection and procedures for the disposal of potentially infective material;
- (iii) The organization's contingency plans in case of spillage;
- (iv) Procedures and guidance for ancillary and maintenance staff, contractors and visitors to the work site;
- (v) Maintenance and test procedures for ventilation systems, high efficiency air filters, microbiological cabinets and other safety equipments;
- (vi) Operations and maintenance of specialist equipment;
- (vii) Procedure for work in particular facilities especially for work activities involving organisms which present particular hazard to human health;
- (viii) Systems and procedures for health surveillance;
- (ix) Organizational procedures for reporting accidents occurring at workplaces, and ;
- (x) Duties and responsibilities of competent persons such as biological safety officers.

## **4. SYSTEM TO HANDLE NOTIFICATIONS/REQUESTS**

The Gambia is a party to the Convention on Biosafety and signed the protocol on the 24<sup>th</sup> May 2000 (Nairobi/Kenya) and finally acceded to the Cartagena Protocol on Biosafety on 09<sup>th</sup> June 2004. The protocol has several provisions that could assist the Gambia to build the relevant human resources and undertake infrastructural development through financial and technical assistance from developed countries. Importantly, the protocol encourages developed countries to assist developing countries like the Gambia in facilitating information exchange, training and providing financial assistance for the implementation of the protocol.

The adoption and use of modern biotechnology may have great potentials in ensuring national food security, it must be developed and use with caution. Due to the potential risks associated with the technology including the magnitude and scope of the consequences to human and animal health and the environment which may be very serious and the effects irreversible, the option for the Gambia is to take a precautionary approach.

### **4.1 Existing System of Notification/Authorization**

In the absence of a National Biosafety Framework and the subsequent lack of the necessary government policies, appropriate legal instruments and administrative mechanisms to adequately regulate biotechnology, no system of notification and or authorization exists to regulate any possible introduction and use of biotechnology or its by-products in the Gambia. Most of the acts and regulations are silent on biotechnology and its products.

It is accepted that genetically modified organisms can ensure the rapid fulfillment of food security for the Gambia, which is in line with the current government policy thinking on food security. But the unregulated use of GMOs is perceived to be associated with short, medium and long-term risks to both human and animals; and the environment. Within the strategic framework of the public and private sector participation in research and development of biotechnology, it is prudent that the Gambia establishes appropriate institutional structures and coherent acts and legislations to regulate the use of GMOs.

#### **4.1.1 Establishment of Biosafety Framework**

The divergent views associated with the various aspects of genetically engineering raises problems on the real and or potential risk posed on human and animal health, and the environment. The health or environmental impact considerations do not preclude the problems associated to the socio-economic impact of biotechnologies on agriculture and the difficulties of accessing new technological innovations from the north. The potential and real risks associated with biotechnologies have led many developed and developing countries alike to adopt the Codex Alimentarius which defines the rules of sanitary control of food including those of transgenic products. The Cartagena Protocol regulates the cross-border movement of genetically modified organisms.

The proper surveillance of the production and dissemination of genetically modified organisms, and the monitoring measures are possible through the establishment of an appropriate Biosafety framework including a detailed procedure for evaluating the health and environment risks. The establishment and maintenance of an efficient Biosafety mechanism requires a transparent and reliable procedure which must include information and public participation in the decision making process. Such a system also requires adequate public sensitization and proper coordination between the various Government State Departments and their technical Departments, the University and other Research related institutions, the private and the general public. Without doubt considerable human, financial resources and scientific equipments will be required to enhance the scientific and technical capacities of all relevant institutions including laboratories. In order to minimize the risks on human and animal health and/or the environment and in consideration of the government's international commitments, it is the obligation of government to urgently put in place the relevant regulatory and legislative requirements.

It is within this background that it is proposed that a Biosafety Authority be established in the Gambia with adequate powers to evaluate and regulate the use of GMOs.

## **4.2 Proposed Institutional Framework**

### **4.2.1 National Biosafety Authority**

As an urgent legal and administrative measure, it is proposed that a **Gambia National Biosafety Authority (GNBA)** headed by an Executive Director be urgently established under the office of the President of the Republic of The Gambia. In addition to the National Biosafety Authority, it is proposed to establish a National Biosafety Technical Committee (NBTC), which will serve as a technical committee responsible for evaluating all applications and or notifications for GMOs. It will determine and communicate to the GNBA the potential and or real risks on human and animal health and/or the environment resulting from the importation, use in restricted areas, and voluntary dissemination in the environment; and the marketing of genetically modified organisms in the country. It is proposed that the Gambia National Biosafety Authority should consist of not more than 9 persons including the following members:-

- (i) A representative of the office of the President,
- (ii) Department of State responsible for Agriculture; and Natural Resources, Fisheries and forestry,
- (iii) Department of State for Education,
- (iv) Department of State for Trade and Industry,
- (v) Department of State for Justice,
- (vi) Department of State for health,
- (vii) Research and Research related institutions (NARI, MRC, ITC, University of the Gambia etc),
- (viii) Focal point for Biosafety Working Group; and,

- (ix) Representatives from civil society (Biosafety specialist, Lawyers).

The Executive Director and members of GNBA may be appointed based on their competence/relevance to biotechnology and on a fixed term basis and such appointment may be renewed once only and, may be terminated only on the recommendation of GNBA. Importantly, among other things, adequate provisions need to be put in place in the statutes for members of the proposed GNBA not to be arrested or prosecuted for decisions taken or opinions held in the performance of their duties. Due to limited resources within state coffers, the Government of the Gambia (GOTG) can approach developed countries and international organizations to provide financial and technical assistance to meet the administrative and technical support cost of the GNBA.

The Executive Secretary of the proposed GNBA will serve as focal point on Biosafety matters and will work closely with the **Secretariat of the Cartagena Protocol**. It is proposed that the authority should undertake the following duties:-

- (i) Define the criteria and regulations for achieving the objectives of the Biosafety policy and act,
- (ii) Implementing the administrative rules and regulation for handling of requests for notification or authorization,
- (iii) Receive request for authorization of importation, exportation, safe handling, restricted use, dissemination or marketing of GMOs or their by-products,
- (iv) Verify the accuracy of the information required for notifications on Biosafety issues,
- (v) Inform all State Departments and other relevant agencies upon the receipt of application for notification or authorization,
- (vi) Urgently submit all applications for notification or authorization to the Biosafety Technical Committee for subsequent evaluation of risks associated with the application,
- (vii) Examine the report of the Biosafety Committee and approve or reject the application on the basis of the committee's findings,
- (viii) Urgently inform all concerned State Departments, public and private sector actors as well as the International Centre for Exchanges on Biosafety on the outcome of the application for notification or authorization,
- (ix) Compile basic data on GMOs and their by-products and make available such data to the general public upon request,
- (x) In collaboration with the State Department for Justice, develop proposals for legislative amendments to ensure the continued minimization of risks associated with biotechnology development and use; and,
- (xi) Submit annual reports to the President of the Republic of The Gambia on the detailed activities of the Gambia National Biosafety Authority.

#### **4.2.2 National Biosafety Technical Committee**

The National Biosafety Technical Committee acts on behalf of the GNBA and is responsible for evaluating health and environmental risks associated with the importation, exportation, safe handling, restricted use, distribution or marketing of GMOs or GMO by-products. Membership of the committee should be large enough to ensure popular participation without compromising the technical efficiency of the committee. While membership of this committee can be increased as the need arises, it is proposed that initial membership be limited to not more than 15 persons including the following:-

- (i) Designated individuals with relevant qualifications and special competence in the area of gene technology, protection of human and animal health, agronomy, environment, legal and trade matters,
- (ii) Representatives from the public and private sectors involved in the importation, safe handling, exportation, restricted use and distribution and or marketing of GMO and GMO by-products; and,
- (iii) Representatives of NGOs, consumer associations, environment protection agency, producer and Community Based Organizations, traditional and religious leaders and the media (both public and private).

The National Biosafety Technical Committee which is a consultative body is designed to perform the following technical functions:-

- (i) Evaluate the risks posed by GMOs as well as the potential dangers linked to the use of gene technology,
- (ii) Advising the Gambia National Biosafety Authority on risks associated with the use of modern biotechnology,
- (iii) Providing scientific and technical information required in the decision making process,
- (iv) Analyzing the potential environmental, socio-economic, trade and public health related risks associated with the large scale dissemination of GMO and GMO by-products; and expressing technical opinions on the socio-economic impact of the introduction of GMO and GMO by-products,
- (v) Promptly liaise with Gambia National Biosafety Authority on all suspected cases of illegal introduction, manipulation, use and voluntary dissemination of GMO and GMO by-products in the country; and,
- (vi) Undertake the monitoring of the restricted or general release and marketing of GMOs and GMO by-products. Ensure that each approved authorization is implemented as per conditions of approval and all unauthorized use of GMOs and GMO-by-products are promptly reported to the GNBA for necessary action.

### **4.2.3 Administrative Procedure**

The GNBA headed by an Executive Director is specifically responsible for the day to day administrative operations and management of the authority including such activities as coordination of public sensitization activities, preparation of reports, receipt and evaluation of applications and above all, ensuring that minimum risks to human and animal health and environment is always maintained. In the process of approving or rejecting each application for notification or authorization, a quorum of the membership must always be maintained during deliberations of the authority. Depending on the extent or volume of the applications, the authority may meet at least once a month and as frequently as is feasible. The decisions of the authority should be based on a simple majority of the members present and vote of the Executive Director will become necessary in case of a tie in the voting process.

In all cases, decisions taken by the authority shall be communicated in writing through a memorandum duly signed by the Executive Director and the Permanent Secretary of the State Department for the Environment and such decisions must be promptly communicated to the applicant irrespective of the status of the decision. Importantly, the authority should necessarily enjoy autonomy in its decisions, which should be final and cannot be revoked by any person(s) or authority. The autonomy of the authority is necessary to ensure that it carries out its duties without fear of prosecution.

The authority shall operate as a public sector institution and Government would therefore be expected to provide adequate annual subventions to the authority. In addition, the authority shall coordinate the consultative process between local communities and academic or commercial researchers and bio-prospectors wishing to access biological resources, indigenous knowledge and technologies within the country. It shall receive part of the benefits to cover its administrative and operational cost. The authority shall also receive income from the issuance of permits and licenses. The Authority shall also seek funding from other international organizations to address specific needs such as training of the personnel in modern biotechnology and related fields of study, provision of relevant equipment and technical assistance to fill short-term gaps.

For the ease and transparency of the accounting system, the authority shall streamline its accounting system to be in line with other public sector institutions and such accounts shall be subject to annual audits by certified independent firms outside the main the government audit department.

Members of the GNBA and NBTC are public officials performing public functions and undertaking responsibilities with the overall intention of carrying out such responsibilities with the best of intentions and in the national interest. Due to the nature of Biosafety work, such public officials can be open to personal danger from the extremist and they need to be adequately protected in the performance of their responsibilities. In addition to immunity from personal prosecution, it is Government's overall responsibility to ensure security for members of GNBA and NBTC, monitoring agents and their families against individuals or organizations that feel injured by the decisions of the Authority or the technical committee.

### 4.3 Technical Requirements for Notifications/Authorizations

In the process of handling requests for notifications or authorization, it is proposed that the following details be obtained for use of genetically modified organisms either in restricted or non-restricted areas and for the importation and marketing of GMO or GMO-by products in the Gambia:-

**4.3.1 Authorization for use of GMOs in Contained Areas:** Applicants requesting for authorization for the use of GMOs in restricted areas in the Gambia will be required to provide detailed information on:

- (i) Name, address, professional qualifications of persons responsible for the implementation of the request for Use of GMO in restricted areas,
- (ii) Scientific name of the GMO and the species to be used,
- (iii) Nature and source of the vector,
- (iv) Method of genetic transformation to be used,
- (v) type of selection marker used,
- (vi) Description of the new genetic resources; and,
- (vii) Description of phenotypic characteristics.

**4.3.2 Authorization for use of GMO in the Environment:** However, request for notifications or authorizations in the use of GMOs in the environment, in addition to information required under use of GMOs in restricted areas, the applicant will provide the following information:-

- (i) Description of ecosystems where GMO or products of such organisms could be disseminated,
- (ii) Description of the identification, detection and drawing techniques,
- (iii) Duration of the dissemination; and,
- (iv) Previous evaluations of environmental risks associated with the dissemination of the concerned GMO or GMO by-product.

### 4.3.3 Authorization for Importation of GMO and GMO-by products

All applications for the importation and marketing of GMOs or GMO-by products in the Gambia should contain the following details: -

- (i) Name and address of the applicant,
- (ii) The scientific name of the GMO or GMO by-product,
- (iii) Name and source of vector,
- (iv) Method of genetic transformation used,
- (v) Type of selection marker used,
- (vi) Description of the genetic characteristics,
- (vii) Type of expected usage (industrial, agricultural, specialized marketing or commercial marketing intended for the general public),

- (viii) Description of the method of identification, detection and drawing techniques utilized,
- (ix) Previous evaluation of risks associated with the marketing of the GMO or GMO by-product (health considerations such as the toxic and or the allergic nature of the GMO or GMO by-product), and;
- (x) A description of the characteristics of the medium in which the GMO or GMO-byproduct is transported.

The Biosafety authority in the evaluation of requests for notification or authorization should evaluate such request in relation to the risk they may pose on human and animal health. Such evaluation should consider other risks such as toxicity, undesirable nutritional effects, resistance to antibiotics among others.

The requests should also be evaluated for environmental, socio-economic, commercial; and, ethical considerations associated with the use and duration of the GMO in question.

#### **4.4 Receipt and Acknowledgement of Receipt of Application**

Upon receipt of an application for notification and or authorization, it is proposed that the GNBA urgently verifies the information contained in the application and ensure that the information provided meets the basic standard set by the authority which should be strictly based on the legal framework approved by the National Assembly and accented to by the President of the Republic of The Gambia. The authority will as a procedure acknowledge receipt of the application within 90 working days. However, if in the opinion of the authority, the application submitted is incomplete or the authority requires additional information, the applicant will be duly notified and the additional information provided before any final decision is made. Written communications to the applicant should be copied to all the relevant Departments of State and in order to ensure public participation and transparency in the decision making process, the general public needs to be informed. The public and private television and radio stations, the print and the electronic media will be useful for information dissemination.

The completed applications which have been subjected to internal verification by the authority are referred to the National Biosafety Technical Committee (NBTC) for evaluation. The NBTC examines the information contained in the application and may request for additional information if necessary. Following a complete health and environmental risk assessment, the NBTC submits a written report to the GNBA expressing its professional opinion on the application accompanied with detailed recommendations. The NBTC will propose detailed voluntary and obligatory measures to be undertaken by the applicant and government in order to prevent risk to human and animal health and the environment.

Since biotechnology is a controversial subject and despite its potential advantages to socio-economic development, caution needs to exercised to avoid health or environmental injury. It requires total public and private sector participation in the entire process. Upon receipt of an application for notification and or authorization, the GNBA will submit the application to

NBTC and simultaneously invite statements from the public and interested organizations on the request to import, restricted use, distribution and marketing of GMOs and GMO by-products. The written statements from members of the public and organization must be received within 30 days. The time limits are necessary to ensure that the applications are urgently given the due attention deserved.

The Gambia National Biosafety Authority having duly considered (i) the information provided by the applicant, (ii) considered the result of the scientific risk evaluation conducted by the NBTC, (iii) considered the economic and socio cultural impacts from the use of the organism; and (iv) the public opinions gathered on the application, will duly notify the applicant within 180 days of its decision to approve or reject the application. Irrespective of the confidentiality of the information concerning notifications to the GNBA, such information will be properly documented and classified at the level of the authority. Furthermore, the GNBA will communicate their final position on each application to the applicant and to the Secretariat of the Cartagena Protocol. In cases where the application is rejected, the authority will provide detailed justifications for its decision to reject the application.

## **4.5 Risk Assessment**

Biosafety risk assessment and risk management is comparatively a new innovation designed to facilitate the safe use and application of modern biotechnological tools. It is argued that biotechnology can ensure rapid increases in food production to meet the demands of increased population. Despite the convincing arguments presented, there has been persistent calls for careful and properly thought out strategies for release of GMOs in our environment. The potential that GMOs or GMO by-products with novel traits may pose danger to both human and animal health and the environment is real.

Therefore, in the submission of applications to the GNBA, the applicant is expected to submit risk assessment documents, which provide detail information relating to human/animal and environmental risks associated with the GMO in question. The risk expected to be covered in the submission are those associated with:-

### **4.5.1 Human Health Related Risks**

- (i) Hazards associated with the host/recipient including pathogenicity of the host strain (virulence, infectivity and toxicity. The presence of harmful agents should be considered especially when using cell cultures),
- (ii) Hazards arising from the inserted genes especially when they contain biological properties likely to give rise to hormones, toxins, allergens etc),
- (iii) Hazards arising from the alteration of existing pathogenic traits (increase in infectivity, mutation etc),

## **4.5.2 Environment Related Risk**

It is difficult to set out detail criteria for assessing environmental risk emanating from the introduction of GMOs in a contained environment or in the case of a general release of GMOs. Notwithstanding the difficulties, actual harm can result from release of GMOs and the following procedures are therefore recommended to undertake environmental risk assessment prior to the release of GMOs:-

- (i) A comprehensive description of the potential hazard that may result from the release of GMOs to the environment,
- (ii) Assessment of the possibility of continued persistence in the environment and their impact on non-transgenic plants and any other impact of the released GM plant to environment,
- (iii) Conduct a pre-release survey of physical and biological risk in order to identify all significant hazards and their associated risk of occurrence e.g. killing of non-target insects by insect resistant plants,
- (iv) Determination of risk associated with GMO plant dispersal and their potential harm to the environment; and,
- (v) Risk management procedures, monitoring mechanisms, contingency plans in cases of emergencies and safeguards required to prevent risk.

## **4.6 Suspension or Cancellation of Authorization**

GMOs and GMO by-products even after careful evaluation by the NBTC and after approval, unforeseen health and/or environmental risk may still emerge. Sufficient legal provisions should be put in place to empower the authority to suspend the authorization at the expense of the holder until such time that adequate supplementary information is obtained for the withdrawal of the product(s) from the market and subsequently prohibit their use. The authority in such cases should be empowered to impose changes to conditions of the voluntary dissemination hitherto allowed in the authorization. The authority shall have the overall mandate to order for the destruction of the GMO or GMO by-product especially in case of the insolvency of the holder of the authorization.

## **4.7 Administrative and Legal Recourse**

Individuals and organizations that obtain authorization shall legally be held responsible for informing the authority about any new elements likely to change the health and environmental risk evaluation undertaken. Non adherence to the administrative and legal provisions resulting in injury to health and the environment will empower the Authority to (i) request the holder of the approval to deposit sufficient money in a commercial bank commensurate to the corrective measures to be undertaken, (ii) levy a penalty on the individual or organization for the performance of the prescribed corrective measures and or (iii) suspend the authorization until such time that the prescribed corrective measures are performed accordingly.

Measures of suspension, withdrawal of authorization or prohibition of restricted use, dissemination or marketing of GMO and or GMO by-products given by the Authority will be carefully monitored and defaulters severely penalized for their disregard of the Authority's legal mandate. The unlawful or unauthorized import, use in restricted areas, intentional dissemination into the environment, marketing of GMO and GMO by-products in the Gambia shall equally draw strict administrative and legal sanctions in commensurate with the extent of the injury inflicted. Adequate legal provisions will be in place to ensure that individuals or organizations injured by the decisions of the authority will have legal recourse for adjudication and final compensation.

## **5. MONITORING AND ENFORCEMENT**

A system for monitoring the release of genetically modified organisms does not exist in the Gambia. The current monitoring system is limited to the inspection of imported food items designed to ensure that qualitative food products are sold in the markets. The implementation of the existing monitoring system however, appeared to concentrate on the expiry date of food items, particularly packaged and canned food items, instead of monitoring schedules associated with the release of genetically modified organisms. A dual system of monitoring is being proposed for the release of GMOs in the Gambia Viz: -

- (a) Voluntary monitoring undertaken by the applicant intending to release GMOs in the Gambia.
- (b) Monitoring required by government for applicants intending to release GMOs in the Gambia; and,

### **5.1 Voluntary Monitoring**

Following the submission of the request for release of GM plants with all the relevant assessment documents, the applicant is required to undertake voluntary monitoring in order to provide additional information relating to the following:-

- (i) A program of release proposal by accumulating data on the survival of the plant in the environment; and,
- (ii) Obtain data in order to address any possible uncertainty in the risk assessment.

The above guidance does not alter the requirement to comply with the general requirement of providing care to prevent risk to the environment which may result in the release of the GM plant. Furthermore, most releases which are not classified as zero risk to environment will most certainly require appropriate monitoring to ensure that no harm results from the release of the GM plant.

### **5.2 Monitoring Required By Government**

The monitoring system required by Government is designed to confirm assumptions made in the risk assessment documents at time of submission of the application for the intended release of GMOs. It will also ensure that products do not enter the human or animal food chain prior to approval by government acting on the advice of the Gambia National Biosafety Authority. The precise design of the monitoring system will to a great extent depend on the details of the risk assessment to be undertaken. Irrespective of the details of the monitoring system, two monitoring schedules are proposed under this category (i) Monitoring during Release and; (ii) Post Release Monitoring.

#### **5.2.1 Monitoring During Release**

Despite a thorough risk assessment of the application for the release of a GM plant, unforeseen developments may still occur which the designed monitoring system may or may not be able to detect. In situations where unforeseen or unplanned developments occur, their significance should be assessed. The primary purpose of establishing a monitoring program during the release of GM plants is to assess the practical efficacy of the adopted safeguards. The risk assessments undertaken should identify the potential safeguards and established the necessary risk management procedures required to minimize risk to an acceptable level. The frequency and coverage of the monitoring system should be adequate enough to ensure that safeguards that are applied are effective and realistic.

## **5.2.2 Post-Release Monitoring**

Post release monitoring is undertaken after the release of the GM plant is completed and the plants are harvested. After the harvest of GM plants, the release organism and or the inserted gene may or may not be present in the release environment in the form of un-germinated seeds, seeds that are shed on the ground or other plant material capable of regeneration. The risk assessment document should have identified the most likely possibilities. Importantly, the extent and/or the frequency of the monitoring program will vary according to the type of plant used in the release, the novel trait expressed and the conditions of the release experiment. The post release-monitoring program will also depend on the possible continued presence of the GM plant or the inserted gene (if transferred into new plants after harvest of the GM crop) that it may cause harm after termination of the trial. Applicants have a continued obligation to comply with the general duty of care to prevent any potential risk to the environment upon termination of the release. Consequently, if the risk assessment undertaken identifies the possibility of harm after the termination of the trial, a suitable monitoring program should be designed to (a) ascertain that the experiment has been terminated and that the released organism is absent after the end of the trial and if required (b) monitor for any further dispersal of the plant, its propagules, pollen or the inserted gene including any necessary control measures.

The release of the GM plant could form part of a series of experiments in a single work program submitted for approval. In such instances, the proposed monitoring system should reflect any changes in the safeguards, which the applicant intends to, apply to the different experiments during the release. Any uncertainties associated with risks or other aspects of the work program are best addressed at an early stage and can ensure the quick relaxation of many safeguards.

Some risks may be dependent on the level (scale) of the risk such as effective dispersal area or increased isolation distance. The need for safeguards may increase if the risks are found to be greater than low. A carefully designed monitoring system should provide adequate data to support future releases and commercialization by demonstrating the safety of the GM plant in the environment.

## 5.3 General Guidelines for a Typical Release

This general outline of a typical release is particularly relevant to releases in the managed environment characteristic of agricultural enterprises (including horticulture). The monitoring methods to be designed and implemented will vary from release to release depending primarily upon the assessed risks and the management of the individual release. However, guidelines provided below must not be regarded as definitive. It should be understood that real release programs, which appear to be similar, may require different risk management elements, depending on the risk assessment conducted.

### 5.3.1 Risk Assessment and the Pre-Release Survey

The first step in the risk assessment is to determine if any potential or real hazards associated with the proposed release do exist. For example:

- (i) The risk of an insect resistant plant harming non-target insects such as bees or the introduction of an insect resistant plant leading to the emergence of a population of insects resistant to insecticides or,
- (ii) The formation of herbicide-tolerant weed population by introgression and subsequent dispersal of the inserted gene characters in the wild or feral relatives.

The introduction of insect resistant plants or formation of herbicide tolerant weed population may have significant negative impact on the ecosystem and the environment if adequate care is not taken. Considering that farmers grow crops in the fields and insects constitute an important part of the crop production cycle taking into account that some insects feed on the plants but other useful insects such as bees facilitate the pollination of the plants. Without the necessary crop and weed types some harmful insects will perish but other useful insects that also feed on the harmful insects will in the long run also perish resulting in a serious in-balance in the ecosystem.

With the identification of the hazards and the methods of the realization, a qualitative assessment of the magnitude of the possible harm must be made and that the identified hazards may result in damage to the environment. Such likelihoods may be categorized as high, medium, low or negligible and the risk of damage may be high, medium, low or effectively zero.

All identified hazards that may arise from the release of the GM plant should be urgently addressed to avoid damage to the environment. These hazards are mainly related to the risks associated with genetically modified organisms that have a potential to cause harm. A key element of the risk assessment is to examine the environment in which the release is to take place and determine the hazards likely to be released. The pre-release survey is therefore an essential part of this examination. The extent and depth of the survey should be designed in such a way that sufficient data is generated to satisfy all the concerns raised and are thoroughly addressed in the risk assessment. In cases where the pre-release survey does not generate sufficient data to address all the concerns, risk management safeguards will be required not

withstanding the status of risk (high, medium, low or uncertain). In case of a GM plant, which is insect resistant, trap plants could help ensure that pollen from the transgenic plant is trapped and does not travel great distances.

If dispersal is a cause of concern, then isolation of the release plot from compatible crop species should be considered as an option. Isolation could be physical (physical distance or biological) by avoiding or preventing the GM plant from flowering simultaneously with compatible species in the surrounding area. Other factors, which need to be considered, include: -

- (i) The plant species released, volunteer crops and feral populations; and compatible wild relatives and visits by other pollinators or other fauna may also be relevant; and,
- (ii) The release plot and the designated dispersal area should include all plants that can be expected to be recipients of the pollen from the GM released plant.

The determination of the dispersal area could be tricky depending on whether the GM plant been introduced is wind or insect pollinated. For instance, in the case of wind pollinated GM plants, the estimated dispersal area might include nearby plots or fields and the dispersal area will to a great extent depend on the size of the release plot or the number of plants contributing to the pool of pollen. On the other hand, for insect pollinated plants the availability of insect pollinators such as bees will be important in the determination of the dispersal area.

The obvious presence of a high population of receptive plants in the immediate vicinity surrounding the trial site including crops grown for seeds and their wild relatives, will contribute to the extent of the area to be classified as dispersal area. There exist possibilities that the pre-release survey will not provide sufficient information to address the uncertainty identified by the risk assessment. In such cases, risk management may be required to ensure that harm does not arise in which situation stringent monitoring will be required to ensure that management procedures are followed effectively.

While the introduction of GM plants in our agricultural production system has the potential to significantly increase food production to feed the ever increasing population, the continued uncertainty about the persistence and spread of GM plants in the environment remains a reality. If only the spread was at some point in time judged to be injurious to human health and the environment, then urgent management safeguards will be required to prevent the spread from occurring. The effectiveness of the monitoring system to be developed should therefore be able to indicate that such a spread has not taken place.

### **5.3.2 Monitoring During Release**

The monitoring during release like the voluntary monitoring required, should be designed in such a way that it will effectively assess the efficacy of any potential risk management safeguards to be applied to the release. The monitoring system should be able to detect the potential risk of injury caused as a result of introgression with potential recipients. For

instance, if it is determined that there exist pollen recipients within the dispersal area, their number should be kept below the level at which harm might occur. The frequency of the monitoring system should therefore consider the growth rate and stage of maturity of the relevant plants. The data acquired during and after the release from such voluntary experiments to test the persistence of GM plants could help address the uncertainty. A more precise risk assessment could then be made for a subsequent release proposal and at the same time reduce the risk management safeguards.

### **5.3.3 Post Release Monitoring**

With the confirmation of the presence of the released GM plant or the confirmation that the gene presents harm to the environment, the post release monitoring to be undertaken will need to concentrate on confirming the removal of the released GM plant. As and when necessary, the monitoring system in such situation should be able to detect the presence of and record the removal of any volunteer plant arising from the release. The uncertainty relating to the risk of harm may occur from the continued presence of GMOs especially over the long term and the post-release monitoring system should be designed in such a way to provide data to enable the uncertainty to be resolved. The seasonal effects such as likely germination and flowering times, post trial treatment of the release site and the longevity of the seeds/tubers in the soil are important factors to be considered.

In general, where flowering is identified as a risk which can result in harm by the gene spread, the monitoring visits should be planned to coincide with the potential flowering times of the volunteer plants. With the determination of the existence of volunteer plants, the dispersal area need to be closely monitored for potential pollen recipients and their off-springs, and such plants should be destroyed. A properly designed monitoring system should be able to provide sufficient information on the extent and duration within which transgenic plants can continue to appear and such information will assist in the determination of the duration of the post-release monitoring that will be required. Estimates of survival times for volunteers should take into account the effects of the volunteer control practices applied to the released site. Finally, the extent and duration of the monitoring period should be sufficient to prevent or minimize damage to the environment over longer term

## **6. MECHANISMS FOR PROMOTING AND FACILITATING PUBLIC AWARENESS, AND EDUCATION.**

### **6.1 Current Level of Public Participation**

Public awareness in the Biosafety framework development process has so far been limited to the establishment of a Biosafety Working Group (BSWG) in 2004, consisting primarily of government institutions such as agriculture, Natural Resources, Research Institutions (NARI, ITC and MRC), Medical and Health, Justice and a few private sector organizations (Radville farm, Makasutu Nature Reserve and NaNa). BSWG prepared the thematic papers and provided guidance and coordination in the development of the overall Biosafety framework. However, members of this working group hold full-time jobs and their participation in the working group is usually in conflict with their official functions. This situation resulted in the delay in holding meetings and the submission of technical reports.

Unfortunately the majority of the policy makers, National Assembly members and the general public (including NGOs/CBOs and farmers) are unaware of the achievements in the use of biotechnology, its potentials in agriculture and health; and the risks associated with the use of the technology. Thus, consultations undertaken are restricted to the working group level and; national and local level sensitization activities are yet to be started. Nevertheless, members of the BSWG all work within the Greater Banjul Area (GBA) and despite their tight schedules, the group undertook the needs assessment and impact evaluation studies.

### **6.2 Proposed Mechanisms for Public Participation**

With the establishment of a National Biosafety Authority, the authority can ensure the active participation of all the stakeholders in the implementation or working stage of Biosafety Authority, particularly in ensuring public participation, conducting awareness raising workshops for farmers and the general public. Such an authority will be expected to undertake the production of documentaries on farm-level activities, radio programs, news letters, posters etc. For the smooth implementation of participatory and awareness creation programs, it is proposed that GNBA should establish an IEC component which will coordinate activities with other collaborating institutions on behalf of the Authority.

### **6.3 Information, Education and Communication (IEC)**

The awareness creation and education component has two major objectives. Firstly, the component will create awareness among all the stakeholders about biotechnology and Biosafety mechanisms, its potentials in the advancement of the agriculture and health sectors and the risks associated with the use of the technology. This support would include national capacity building in biotechnology research and development, development of appropriate

communication techniques, the production and dissemination of suitable information, education and communication (IEC) materials; and provision of adequate infrastructure and equipment to ensure sustainability of biotechnology adoption and Biosafety mechanisms.

Secondly, the component will identify, mobilize and utilize communication resources and make them accessible to all the stakeholders, particularly the farming community in promoting the safe use of biotechnology. Specifically, the IEC component aims to:

- (a) Create awareness and initiate dialogue among policy makers and the other stakeholders concerning the safe introduction of biotechnology within the agriculture and natural resources and health sectors,
- (b) Provide communication support for the country-wide awareness or sensitization activities on Biosafety and ensure public participation in the decision making process,
- (c) Provide infrastructural support for the production and broadcast agencies to make them more responsive to the development needs of the country,
- (d) Establish communication models suitable for the safe handling of biotechnology and Biosafety,
- (e) Provide research support for all Biosafety communication activities to ensure quality production and efficient dissemination and enhance safety,
- (f) Provide feedback to ensure popular participation in the decision making process, design and implement communication activities relating to Biosafety through traditional as well as modern media techniques and serve as source of information for policy makers; and,
- (g) Train a cadre of professionals in all the concerned State Departments and institutions in order that they become familiar with the issues and processes of communication in Biosafety and can effectively plan, implement and evaluate communication activities.

In order to ensure wide-spread and popular participation in the Biosafety decision making process, the IEC component of the proposed GNBA will provide overall communication support to each of the other components identified (Radio and Television Services, Agricultural Communication Unit, Existing Rural Broadcasting Stations, Non Formal Education Unit of DOSE including NGOs involved in adult literacy programs, IEC component in DOSH etc). The support will include the training of personnel, provision of communication equipment, production of Biosafety posters and the provision of infrastructural development necessary for ensuring sustainability

To achieve its objectives, the IEC component will rely on a number of public and private sector institutions in ensuring awareness creation and subsequent wide-spread participation among Gambians within the realm of decision-making associated with the importation, use, safe handling and the marketing of GMO and GMO by-products. The authority will assume responsible for the overall coordination of all IEC support activities in the country. The shared resources will be managed by the authority in collaboration with the targeted units to be responsible for the implementation of the IEC component within each sector as detailed below:

- (i) The Gambia Radio and Television Services representing both radio (including Rural Broadcasting Stations) and television and the print media,
- (ii) Agricultural Communication Unit (ACU) of the Department of State for Agriculture (DOSA). It will also serve the Department of State for Natural Resources, Forestry and Fisheries,
- (iii) Non Formal Education Unit of the Department of State for Education and also responsible for NGOs involved in adult literacy programs; and,
- (iv) The Health Education Unit of the Department of State for health.

The IEC component of the GNBA will require a great deal of time and energy to effectively coordinate all the activities within the various public and private sector organizations on a subject which is relatively new within Gambia's technological development arena. The support will include training and in some cases the retraining of communication personnel, the production and dissemination of communication materials, and the provision of communication materials and equipments. As the nerve center of the information system, this component will undertake extensive coordination at all levels.

#### **6.4 The National Biosafety Authority and Central Coordination**

The overall central coordination responsibility for this component will rest with IEC unit of the Gambia National Biosafety Authority. The unit will undertake technical and technological coordination duties, and will supervise the overall technical implementation progress of the IEC component, coordinate the scheduling of campaigns and media production for the various collaborating IEC units and assist the formulation of messages and the delivery of media content. The IEC component will also assist the Authority in the identification of suitable communication materials and equipment and assume responsibility for their installation.

As part of the overall infrastructural development related to the IEC component, it is proposed that the Authority seeks the services of a qualified and experienced Gambian to serve as Coordinator of the IEC component. At the level of authority, he will be assisted by technically competent personnel with adequate experience in the operation and use of electronic equipment, production of high quality documentary films and graphic materials. With the availability of individuals and firms with adequate reputation in the repair and maintenance of electronic equipment, it is further envisaged that the Authority will hire their services for the overall repair and maintenance of the electronic equipment to be purchased.

The authority will re-activate the novel idea of establishing video halls hitherto provided under the support of the Women in Development (WID) Project and in the process construct permanent multipurpose video halls large enough to accommodate at least 50 farmers, equip them with solar powered VCRs and television sets. Initially, these will be located in 25 large towns and villages spread across the country and will serve as a focus for awareness creation in biotechnology and Biosafety. Relevant documentary films relating to biotechnology, the associated risks and its relevance to agriculture, health and the environment will be screened.

The video halls will also be used for literacy programs designed to create public awareness in biotechnology research and development and Biosafety mechanisms; and also ensure popular participation in the decision making process. The field personnel or extension personnel of the concerned organizations will schedule their visits to the towns and villages provided with video halls in such a way that their visits would coincide with the screening of their materials. This will enable the field officers and extension personnel to adequately respond to questions raised by farmers and or initiate discussions on key topics in biotechnology. The television monitors to be provided should be equipped with sensitive antennas to facilitate the receipt of GRTS television programs and the time of showing of biotechnology and safety programs should be communicated to all the video halls to ensure viewing by the organized groups.

The multipurpose video halls will be placed under the care of organized groups in each town and village. For the purpose of ensuring sustainability, commercial videos can be screened for a reasonable but affordable fee. However, the screening of such commercial videos should not be allowed to be in conflict with the normal biotechnology/Biosafety programs transmitted through GRTS. The proposed 25 video halls, initially to be built during the end of year one of the establishment of IEC component of the Authority, will serve as an experience gathering endeavor in the management of video halls and also allow for adequate time for the production of sufficient video tapes for the use of the video halls. The experience gained in the management of multi-purpose video halls will facilitate their expansion into other villages. In light of the existing television and radio systems, the purchase of equipment and materials should be in line with the operating system available in-country.

The video halls will also be used as radio/cassette listening groups and in addition, 75 other communities will be provided with radio/cassette players. The field visits by extension personnel of the collaborating organizations to the radio listening groups, like video halls will be synchronized to coincide with the airing of biotechnology/Biosafety radio programs. The radio programs produced and aired can be recorded and duplicated and made available to villages upon request for the purpose of individual listening.

The IEC component of the Biosafety Authority will also coordinate the production of posters and pamphlets for all the collaborating IEC units within the collaborating technical units as well as undertake IEC research. One major survey to be undertaken prior to the construction and operation of the multi-purpose video halls will be the implementation of surveys to determine the level of biotechnology and Biosafety awareness of the organized groups. The qualitative and quantitative information collected will serve as baseline data, which will in future be used as a reference point in determining their understanding of biotechnology and the extent of their participation after the introduction of the various IEC tools. The Authority will assist the various IEC units in the targeted technical Departments with the pre-testing of their products/materials, thereby ensuring quality, which is expected to result in increased understanding of the target beneficiaries. The Authority will also undertake impact studies, comparing organizations/target communities hitherto provided with multi-purpose video halls and radio listening facilities with controlled groups designed to determine “what impact” if any, access to these facilities may have on biotechnology as it relates to agriculture and health.

In its awareness creation and participatory activities, the Authority will implement regular IEC workshops for participants representing all relevant sectors. Special workshops will be conducted for the benefit of policy makers, legislators, journalists, traditional rulers and religious leaders to make them more conversant with biotechnology and the safety mechanisms instituted to prevent or minimize risk to health and the environment. In addition, the Authority will host a number of international seminars, conferences and organize study tours within the sub-region for organized groups. It is envisaged that through these conferences, seminars and study tours, biotechnological information including the safety mechanisms can be shared through exchange of views and experiences.

It is anticipated that UNEP/GEF and other bilateral/multilateral and international agencies will provide both short and long term technical assistance (both financial and human resources) to the Authority and other collaborating institutions. Such assistance will continue to be provided until adequate capacity and experience is developed in country to effectively handle biotechnology and Biosafety.

The production of IEC materials, with the exception of those of the Gambia Radio and Television Services (GRTS) and the Agricultural Communication Unit (ACU) will be contracted to various production agencies in the country. The posters and other print materials may be contracted to institutions such as the Book Production and Material Resources Unit and any other private sector institution with adequate and appropriate in country production facilities. On the other hand, despite the availability of private sector individuals and organizations the production of video materials and radio programs will be the sole responsibility of the Gambia Radio and Television Services (GRTS). This is due largely to the extent of the professionalism required to produce technical materials on video and also the larger coverage enjoyed by GRTS. GRTS will further guarantee radio and television support for all the key biotechnology and Biosafety activities. This support will include:

- (i) Radio and television programs such as “live” group discussions aired on television,
- (ii) Radio and television spots in support of sensitization campaigns, duplication of video and radio tapes for use by video halls and radio listening groups,
- (iii) Technical guidance in the operation and maintenance VCRs and television monitors, radio cassette players etc; and,
- (iv) Production of documentary films on various aspects of biotechnology and Biosafety mechanisms.

The Authority will assist GRTS with the necessary technical training to enable the organization to undertake audience surveys designed to improve the quality of their programs. The Authority will also assist GRTS in the procurement of the required equipments, materials and vehicles designed to ensure effective supervision of the video halls and radio listening groups and also ensure the timely production of television and radio programs.

## **6.5 Supports to the Biosafety Authority**

The Gambia National Biosafety Authority has a complex and important task to perform and will therefore require substantial support to make it functionally effective. The Authority will need to be provided with extensive support in the form of office accommodation equipped with telephone lines, computers, photocopying and fax machines, conference facilities and vehicular support. The desk and laptop computers provided should be installed with appropriate “Windows” software programs to assist the Authority with the publication of newsletters, brochures and research software programs suitable for the analysis of survey data. The computers should also be installed with Internet facilities. The central coordination unit of the Authority and the collaborating IEC sub-components appear to have high investment costs. The costs are justified by the fact that the bulk of the costs is designed to ensure that the population is informed and concerned individuals and organizations are effectively participating in the Biosafety decision making processes and it is anticipated that the culture of public participation through the Biosafety process will be extended to other national development endeavors.

## **6.6 Agricultural Communication Unit (ACU)**

The ACU will have an important role to play in the creation of public awareness, education and ensuring of participation in the decision making process of the Biosafety Authority. It has a functioning educational system already in operation, which includes studio and production facilities for videotapes and simple print material. ACU has enjoyed support in the past under series of project interventions, particularly in the Agricultural sector. More recent support to the ACU includes support from the recently terminated Agricultural Services Project and Lowland Agricultural Development Project. Current support enjoyed by ACU includes those provided by the Rural Finance and Community Initiative and Peri-Urban Projects. ACU continues to operate video vans and produced documentary films on agricultural development activities. Support to the unit will constitute such items as video vans, video cameras, modern printing facilities and materials, desktop computers and printers with complete accessories.

ACU will support ongoing field activities performed by agricultural extension workers (including livestock extension personnel), train them in communication process, and provide them with materials needed to conduct extension training. The unit will provide video coverage for the implementation of development activities undertaken by the State Departments of Agriculture and; Natural Resources, Fisheries and Forestry and such video tapes can be televised as part of the agriculture and natural resources radio and television programmes. It will also reactivate the abandoned agricultural newsletter (“**SENELA**”), which is designed to inform the extension personnel on current technological advancements, and also serve as forum for exchange of ideas in the agriculture and natural resources sector.

ACU will also produce video programmes on biotechnology and Biosafety and their overall potential contribution to agricultural development in the country and it will also coordinate its field activities with the Authority particularly for pre-viewing of video tapes to be provided to

the 25 towns and villages hitherto provided with video halls. The other 75 villages provided with radio listening groups will also be covered by ACU's cinema vans.

## **6.7 Health Education Unit**

Support for the public awareness creation and safe use of GMOs in the form of vaccines will be managed by the Health Education Unit (HEU) of the Department of State for Health and Social Welfare. Support in the past concentrated on safe motherhood concepts. The Gambia does not manufacture live vaccines but the Department of State for Health and Social Welfare and Department of Livestock Services under the Department State for Agriculture imports large quantities of vaccines. While GAMVET and AGROVET monitor imports of veterinary vaccines, the Department of State for Health and Social Welfare has no agency responsible for monitoring medical vaccines in country. The public needs to be aware of the import, handling and safe use live vaccines.

The activities of the Health Education Unit will include the implementation of sensitization campaigns on the handling and use of vaccines for both animal and human health. It is envisaged that the unit will undertake staff training in the safe handling and use of vaccines, and develop appropriate training materials (both print and electronic). It is anticipated that the HEU and Divisional Health teams, in addition to the services to be provided by GRTS, will use the 25 video halls and 75 radio listening groups for the dissemination of relevant information relating to safe use of vaccines.

For the creation of public awareness activities, the HEU will be provided with support in the form of video equipment and materials and radio cassette recorders.

## **6.8 Non-Formal Education Unit**

The Non Formal Education Unit of the Department of State for Education will be the lead institution responsible for translating biotechnology and Biosafety materials in local languages and conduct adult literacy training programmes in collaboration with existing Non Governmental Organizations (NGOs) involved in adult literacy/numeracy programs. Most these public awareness activities to be undertaken by the Non-Formal Education Department and other adult literacy/numeracy focused NGOs will comprise of the preparation of suitable print material in the local languages. The costs associated with the production of the print material are exorbitant and will therefore need to be well prepared.

The Non Formal education Department has extensive experience in conducting adult literacy and numeracy programmes and no expatriate technical assistance will be needed. The assistance envisaged will include the initial preparation of print materials; conduct training in adult literacy and numeracy and the training of trainers. The content of its training materials will focus on awareness creation or sensitization on the debate relating to biotechnology and Biosafety mechanisms.

It is assumed that the department has adequate trained personnel and with the collaboration of NGOs involved in adult literacy and numeracy programmes, no additional staff costs other than field-testing of materials are envisaged.

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## **ANNEX 1: Containment and Control Measures for Laboratory and Large-Scale Activities Involving Genetically Modified Micro-organisms (GMMs)**

This section describes the prescribed standard of containment and control measures to apply to work pertaining to laboratory and large scale activities and it should be used in conjunction with the regulatory requirements for determining GMO containment and control measures described above. It is presented for four levels of containment (at both small and large scale activities). While the activities detailed for the various levels of containment are similar across all levels, the stringency and appropriateness of the methods to be used will differ. Potential users will therefore have to decide whether the small or large scale guidance is the most appropriate for each specific activity. The key consideration should be appropriateness of the containment and control measures to be applied. Additional information is also provided on other issues such as micro-biological safety cabinets, disinfection, fumigation etc.

### **1.1.1 Small Scale Containment Levels**

#### **(i) GNBSA Containment Level 1**

In this section, it is recommended that the personnel working in the laboratory should receive relevant information, instruction and training in implementing laboratory procedures. They should also receive appropriate standard and routine supervision in order to ensure that procedures are always followed accordingly. Below is a description of the relevant procedures:

#### **(a) Laboratory Building**

- Under containment level 1, it is not necessary for the facility to be mechanically ventilated. In a well-ventilated laboratory facility, room air may be allowed to filter into the atmosphere without any need for prior filtering.
- However, good hygiene and sanitary conditions should always be maintained. An easy to clean table and bench surfaces will facilitate this process. Such surfaces should be impervious to water and resistant to acids, alkalis, solvents and disinfectants normally used in laboratories.
- Wash hand basins and/or sinks should be provided in the laboratory to facilitate washing of hands before and after work.

#### **(b) Work Practices**

The procedures or work practices detailed below are standard procedures recommended for containment level 1 and should be strictly adhered to in order to ensure safety at all times:

- (i) The laboratory doors and windows should always be closed especially when work is in progress;

- (ii) The laboratory coats or gowns provided should always be worn in the laboratory and immediately removed prior to leaving the laboratory;
- (iii) Gloves should be worn when working especially if indicated in the risk assessment;
- (iv) As a standard procedure, all personnel should always wash their hands before and after work particularly when contamination is suspected after the handling of GMMs and before leaving the laboratory room;
- (v) Laboratory procedures should be carried out in such a way that aerosol production is kept to the barest minimum. In cases where aerosol production is unavoidable, the risk assessment should determine procedures to control exposure of workers and contamination of the environment;
- (vi) Effective disinfectants should be made available for immediate use in the event of spillage;
- (vii) Table surfaces or bench tops and laboratory equipment should be cleaned or disinfected as appropriate after each use;
- (viii) Contaminated laboratory glassware and other materials awaiting disinfection should be stored in a safe manner;
- (ix) All waste materials containing viable GMMs should be disposed of in a safe manner and materials for disposal should be transported in suitable containers without spillage, and;
- (x) All accidents and incidents should be reported to the immediate supervisor(s) and properly recorded.

**(ii) GNBSA Containment Level 2**

In this section, it is recommended that the personnel working in the laboratory should receive relevant information, instruction and training in handling of micro-organisms including GMMs. They should also receive appropriate standard and routine supervision in order to ensure that procedures are always followed accordingly. Below is a description of the relevant procedures:

**(a) Laboratory Building/Physical Measures**

- (i) While there is no requirement to provide separate working areas in the same building, there may be cases when providing separate facilities may be necessary. For example, work procedures for certain viruses may require carrying work activities in a relatively isolated condition. The risk assessment should be used to determine necessity of using partial or separate work areas;
- (ii) Good standard of hygiene and sanitary conditions should always be maintained. The use of easy to clean surfaces will facilitate the maintenance of good hygiene and sanitary conditions. Work bench surfaces should be impervious to water and resistant to reagents and other disinfectants normally used in laboratories;
- (iii) In order to facilitate the washing of hands especially after work in laboratories, wash hand basins fitted with taps that can be operated without being touched by hand should be located near the laboratory exit;

- (iv) For animal containment purposes, vector control systems need to be introduced as part of the measures for the control of rodents and insects as may be necessary. For instance, insect control measures will be needed when working with some insect borne pathogens;
- (b) **Work Practices**
- (v) Where necessary, biohazard signs **must be displayed** detailing out the nature and level of work being undertaken. This requirement will usually be indicated in the risk assessment;
- (vi) Access to the laboratory should be limited to only laboratory personnel and other specified persons. The nature of work will determine which person(s) will be allowed entry to the facilities;
- (vii) Laboratory doors must always be properly closed at all times but more so when work is in progress and if so indicated in the risk assessment. In cases where work on airborne pathogens is undertaken and the laboratory fitted with mechanical ventilation systems, it will be necessary to keep the doors properly closed;
- (viii) Laboratory coats or gowns (preferably with side or back fasteners) should be provided and worn at all times in the laboratory. As a practice, coats should be removed before washing of hands prior to leaving the laboratory. Importantly, sufficient number of pegs should be provided in the laboratory suit to allow for only a coat/gown per peg. Coats/gowns should be changed on a regular basis and must be changed immediately when contamination takes place;
- (ix) As a general rule, hand gloves should be used especially if so required by the risk assessment;
- (x) After the handling of GMMs and before leaving the laboratory washing of hands must be observed as a routine practice. In cases where contamination is suspected, decontamination procedures should be immediately followed;
- (xi) Unless the risk assessment indicates otherwise, work activities can be performed on an open bench but procedures which keep aerosol production to the barest minimum need to be implemented. Where aerosol production is unavoidable, a suitable micro-biological safety cabinet or equipment designed to contain aerosol should be used;
- (xii) In order to facilitate the routine cleaning of bench tops and glassware, effective disinfectants should be available for routine disinfection and immediate use in cases of spillage;
- (xiii) Contaminated laboratory equipment and other materials awaiting disinfection should be stored in a safe manner and all infected waste material should be disposed off in a safe manner. GMMs should be inactivated by validated means prior to disposal. Where contractors are required to remove contaminated waste materials for remote disposal, the contractor and designated disposal site will need to comply with standard regulations, particularly if viable GMMs are handled;
- (xiv) An autoclave for the sterilization of waste material should be readily available. The autoclave would usually be located in the same building as the laboratory;

- (xv) In order to ensure that no spillage occurs, waste and contaminated materials should be transported in robust leak proof containers, and;
- (xvi) All accidents occurring in the laboratory should be recorded and reported to the competent authority, usually a Biosafety Officer, who as part of his responsibility should immediately report to the GNBSA.

(iii) **Containment Level 3**

In this section, it is recommended that the personnel working in the laboratory should receive relevant information, instruction and training in the handling of micro-organisms. They should also receive high standard and routine supervision in order to ensure that procedures are always followed accordingly. Below is a description of the relevant procedures:

(a) **Building Design/Physical Measures**

- (i) The laboratory should be separated from other activities in the same building and it should be located in an area away from general circulation. The degree of isolation should be commensurate with the risk;
- (ii) A continuous airflow into the laboratory should be maintained when work is in progress with air pressure maintained at levels negative to the surrounding atmosphere. It is good practice to make provisions for comfort factors such as fresh air, comfortable temperature and acceptable levels of humidity;
- (iii) A high standard of hygiene and sanitary conditions should always be maintained. The use of easy to clean surfaces will facilitate the maintenance of good hygiene and sanitary conditions. Work bench surfaces should be impervious to water and resistant to regents and other disinfectants normally used in laboratories;
- (iv) In order to facilitate the washing of hand especially after work in laboratories, wash hand basins fitted with taps that can be operated without being touched by hand should be located near the laboratory exit;
- (v) There should be an observation window or door so that occupants can be seen at all times during work. Glass panels in the door is usually sufficient;
- (vi) For animal containment purposes, vector control systems need to be introduced as part of the measures for the control of rodents and insects as may be necessary. For instance, insect control measures will be needed when working with some insect borne pathogens;
- (vii) The laboratory should be sealable to permit fumigation especially during major spillages and or fumigation prior to maintenance of the facility;

(b) **Work Practices**

- (viii) Where necessary, biohazard signs **must be displayed** detailing out the nature and level of work being undertaken. This requirement will usually be provided for in the risk assessment;

- (ix) Access to the laboratory should be limited to only laboratory personnel and other specified persons. The nature of work will determine which person(s) will be allowed entry to the facilities. This may be facilitated by the use of key coded entry systems;
- (x) Laboratory doors must always be properly closed at all times but more so when work is in progress and if so indicated in the risk assessment. In cases where work on airborne pathogens is undertaken and the laboratory is fitted with mechanical ventilation systems, it will be necessary to keep the doors properly closed;
- (xi) Laboratory coats or gowns (preferably with side or back fasteners) should be provided and worn at all times in the laboratory. As a practice, coats should be removed before washing of hands prior to leaving the laboratory. Importantly, sufficient number of pegs should be provided in the laboratory suit to allow for only a coat/gown per peg. Coats/gowns should be changed on a regular basis and must be changed immediately when contamination takes place;
- (xii) As a general rule, hand gloves should be used especially if so required by the risk assessment;
- (xiii) After the handling of GMMs and before leaving the laboratory washing of hands must be observed as a routine practice. In cases where contamination is suspected, decontamination procedures should be implemented immediately;
- (xiv) The laboratory should ideally have its own set of standard equipment such as centrifuge, incubator, refrigerator/deep freezer etc. in order to ensure that viable materials are properly stored and worked on within the laboratory only. For large activities, materials may be transported and stored without spillage in properly labeled containers and such materials should be opened only in containment level 3 laboratory facilities;
- (xv) In the case of tissue culture affecting work involving organisms with airborne route of transmission or in cases of work involving high degree of uncertainty, it may be necessary to use class 3 cabinets. The only exception to this requirement is where the equipment to be used provides containment of the potential aerosol;
- (xvi) In order facilitate the routine cleaning of bench tops and glassware, effective disinfectants should be available for routine disinfection and immediate use in cases of spillage;
- (xvii) Contaminated laboratory equipment and other materials awaiting disinfection should be stored in a safe manner. All infected waste material should be disposed off in a safe manner. GMMs should be inactivated by validated means prior to disposal. Where contractors are required to remove contaminated waste material for remote disposal, the contractor and designated disposal site will need to comply with standard regulations, particularly if viable GMMs are handled;
- (xviii) An autoclave for the sterilization of waste material should be readily available. The autoclave would usually be located in the same building as the laboratory. Although it is permissible for waste materials to be

inactivated by chemical means, it is normally more appropriate to autoclave waste. In the event that chemical disinfectants are used, the disinfection procedure must be validated under the working conditions (use of buffering solutions or proteins). Where incinerators are available, waste can be incinerated following safe transportation. Details of the proposed method(s) of waste management must be supplied to the National Environment Agency and GNBSA;

- (xix) In order to ensure that no spillage occurs, waste and contaminated materials should be transported in robust leak proof containers, and;
- (xx) All accidents, spillage and exposures to infective materials occurring in the laboratory should be recorded and reported to the competent authority, usually a Biosafety Officer, who as part of his responsibility should immediately report to the GNBSA.

(iv) **GNBSA Containment Level 4**

Due to the high risk involved, this section assumes a requirement to protect both the personnel and the environment. It is recognized that work with certain animal or plant pathogens may require very high levels of environmental protection, often with little attention to the personnel. In recognition of this fact, the entire laboratory block is considered to be at level 4 for environmental protection but with proviso that the employee can operate on an open bench or in an open fronted cabinet. Containment level 4 is generally reserved for work with organisms such as foot and mouth disease and Rinderpest viruses. Due to the more technical nature of Containment level 4, specific sets of rules which can be easily implemented should be developed.

Personnel should have specific training in the working of the laboratory, the safe use of the equipment and should receive relevant information on the handling of the micro-organisms concerned. Adequate supervision should always be provided. Below is a description of the relevant procedures:

(a) **Building /Physical Measures**

- (i) The laboratory should be a separate building or it should be located in an isolated part of the building allowing for little or no general circulation. The degree of isolation should be commensurate with the risk;
- (ii) A continuous airflow into the laboratory should be maintained when work is in progress with air pressure maintained at levels negative to the surrounding atmosphere. It is good practice to make provisions for comfort factors such as fresh air, comfortable temperature and acceptable levels of humidity. The ventilation system should incorporate a system of preventing reverse airflows. The supply and extraction of airflow should be interlocked to prevent positive pressurization of the laboratory in the event of failure of the extract fan and an emergency (backup) source of electricity supply should be provided to cut in automatically in the event of power failure;

- (iii) An extremely high standard of hygiene and sanitary conditions should always be maintained. The use of easy to clean surfaces will facilitate the maintenance of good hygiene and sanitary conditions. Work bench surfaces should be impervious to water and resistant to reagents and other disinfectants normally used in laboratories;
- (i) A system of communication within and outside the laboratory should be maintained. Telephone lines, fax or computer connections can be useful for safe transfer of data and information;
- (ii) In order to facilitate the washing of hand especially after work in laboratories, wash hand basins fitted with taps that can be operated without being touched by hand should be located near the laboratory exit. In addition, shower facilities should be provided to allow personnel to shower (including washing of hair) prior to leaving the building;
- (iii) There should be an observation window or door so that occupants can be seen at all times during work. Glass panels in the door are usually sufficient;
- (iv) For animal containment purposes, vector control systems need to be introduced as part of the measures for the control of rodents and insects as may be necessary. For instance, insect control measures may be needed when working with some insect borne pathogens;
- (v) The laboratory should be sealable to permit fumigation especially during major spillages and/or fumigation prior to maintenance of the facility;

(b) **Work Practices**

- (vi) Biohazard signs **must be displayed** on the outer door to the laboratory unit detailing out the nature and level of work being undertaken. **“Work in Progress”** sign should be displayed. This requirement will usually be provided for in the risk assessment;
- (vii) Access to the laboratory should be limited to only laboratory personnel and other specified persons. The nature of work will determine which person(s) will be allowed entry to the facilities. This may be facilitated by the use of key coded entry systems;
- (viii) Laboratory doors must always be properly closed at all times but more so when work is in progress and if so indicated in the risk assessment. In cases where work on airborne pathogens is undertaken and the laboratory is fitted with mechanical ventilation systems, it will be necessary to keep the doors properly closed;
- (ix) A complete change of clothing is to be worn in laboratory unit. The clothing is to be removed after work in the dirty side of the changing room area and place in containers for autoclaving. High performance respiratory protective equipment need to be available for use during emergencies;
- (x) Procedures for emergency evacuation should be drawn-up and practice drills of such procedures undertaken at least once a year to ensure that all personnel are fully capable of using the procedures;
- (xi) As a general rule, hand gloves should be used especially if so required by the risk assessment;

- (xii) After the handling of GMMs and before leaving the laboratory, washing of hands must be observed as a routine practice. In cases where contamination is suspected, decontamination procedures should be implemented immediately;
- (xiii) The laboratory should ideally have its own set of standard equipments such as centrifuge, incubator, refrigerator/deep freezer etc. in order to ensure that viable materials are properly stored and worked on within the laboratory only.
- (xiv) In the case of tissue culture affecting work involving organisms with airborne route of transmission or in cases of work involving high degree of uncertainty, it may be necessary to use class 3 cabinets. The only exception to this requirement is where the equipment to be used provides containment of the potential aerosol;
- (xv) In order to facilitate the routine cleaning of bench tops and glassware, effective disinfectants should be available for routine disinfection and immediate use in cases of spillage;
- (xvi) Contaminated laboratory equipment and other materials awaiting disinfection should be stored in a safe manner. All infected waste material should be disposed off in a safe manner. GMMs should be inactivated by validated means prior to disposal. Where contractors are required to remove contaminated waste material for remote disposal, the contractor and designated disposal site will need to comply with standard regulations, particularly if viable GMMs are handled;
- (xvii) A double ended Autoclave with interlocking doors should be readily provided. The autoclave would usually be located in the same building as the laboratory. Although it is permissible for waste materials to be inactivated by chemical means, it is normally more appropriate to autoclave waste. In the event that chemical disinfectants are used, the disinfection procedure must be validated under the working conditions (use of buffering solutions or proteins). Where incinerators are available, waste can be incinerated following safe transportation. Details of the proposed method(s) of waste management must be supplied to the National Environment Agency and GNBSA;
- (xviii) In order to ensure that no spillage occurs, waste and contaminated materials should be transported in leak proof containers, and;
- (xix) All accidents, spillage and exposures to infective materials occurring in the laboratory should be recorded and reported to the competent authority, usually a Biosafety Officer, who as part of his responsibility should immediately report to the GNBSA.

### **1.1.2 Containment and Control Measures for Large Scale Activities**

The containment and control measures for large scale activities which are summarized in table 2 are recommended good practices and/or proposed methods which can be used to determine the level of containment required. It should be understood that the measures contained in this section are only indication of good practice and not regulatory requirements.

#### **(i) GNBSA Containment Level B1**

The principle of good microbiological practice and good occupational safety and hygiene describe for small scale activities in 2.8.1 also apply for this section. It is also a requirement that containment be used to limit the possible contact with the general population and the environment for all Genetically Modified Micro-organisms (GMMs). This requirement is irrespective of the fact that many GMMs which can appropriately be handled at containment level B1 present little risk to human health and the environment. It is also recognized that for lower risk GMMs, the containment for process requirement is more stringent than that needed for human health and the environment. The risk assessment will usually determine the level of containment based on the need to control or prevent exposure to human health and the environment.

**(a) Building Design/Controlled Measures**

- (i) It is acceptable that no separate buildings or controlled areas is required for GMM containment activities but it is reasonable for the factory or production floor areas to be separate from office facilities;
- (ii) Good hygiene and sanitary conditions is recommended and building designs and floor specifications should be easy to clean;
- (iii) While mechanical ventilation is not a requirement, it can be useful for removing heat generated through the production process and such a facility is useful for the comfort of the personnel. For some production processes, a positive air pressure may be needed to maintain product integrity. Use of positive air pressure is acceptable as long as it does not compromise the need to control organisms within the facility in the case of accidents. Localized air flow units which provide adequate protection for both the product and personnel can be considered;
- (iv) It is not necessary for the design of the containment facility to be designed to contain spillage of the contents of a closed system;

**(b) Fermentation Methods, Equipments and Utilities**

- (v) Viable GMMS should be contained in a system which includes physical barriers designed to separate them from the general environment. The risk assessment will usually determine the type of system to select but most activities at containment level B1 would not require a close system. Usually, the building itself will adequately serve as a physical barrier. Equipment such as ventilated flasks, open top fermenters, open mixing vessels, baking tins and trays etc which are used in industrial production facilities are adequate for containment level B1;
- (vi) In order to minimize the contact of GMMs with people and the environment, release of GMMs into the work place and wider environment should be minimized especially during procedures such as (a) when adding materials and (b) mixing or transfer of GMMs between vessels. The acceptable degree of minimization should be determined by the risk assessment. Incases where it is indicated that there is no risk of harm, it is unlikely that elaborate methods of controlling escape will be necessary;
- (vii) Seals to be used in the containment facility should be efficient and durable so that contamination of the work place and wider environment is limited and thereby preventing harm;
- (viii) Equipment and control measures should be tested and maintained at regular intervals;

**(C) Management Systems and Work Practice**

- (ix) Upon recruitment and as a continuous process, personnel should be trained adequately in both routine and emergency procedures. Written operating instructions, emergency plans and spillage policy should be available to all employees;
- (x) Adequate washing facilities should be provided for personnel;
- (xi) Laboratory coats or gowns (preferably with side or back fasteners) should be provided and worn at all times in the laboratory. As a practice, coats should be removed before washing of hands prior to leaving the laboratory. Importantly, sufficient number of pegs should be provided in the laboratory suit to allow for only a coat/gown per peg. Coats/gowns should be changed on a regular basis and must be changed immediately when contamination takes place;
- (xii) Care should be taken to minimize the release of GMMs into the work place during sample collection;
- (xiii) Waste material should be disposed off in a safe manner;
- (xiv) There is no need to treat exhaust gases,
- (xv) While there is no need to have elaborate emergency plans drawn up for containment level B 1, it is good practice to develop procedures to deal with spillages;
- (xvi) All accidents should be properly recorded, and;
- (xvii) Many activities under containment level B 1 will not require monitoring. However, where risk to human health or the environment from organisms

outside the close system exists, monitoring for viable process organisms should be carried out.

**(ii) GNBSA Containment Level B2**

**(a) Building Design/Controlled Measures**

- (i) The risk assessment will usually indicate whether activities under containment level B 2 should be undertaken in a controlled environment or not. Where a controlled environment is proposed, the facility should be separated from the offices, laboratories and other facilities;
- (ii) Good standard of hygiene and sanitary conditions should always be maintained and this can be facilitated by well designed buildings. The buildings should be of normal industrial specifications with sealed impervious floors and standard industrial walls. Floors can be constructed with non porous concrete to facilitate its cleaning. Walls and ceilings should be covered with resin bonded fiber;
- (iii) The risk assessment may indicate ventilation as a requirement and in such cases the controlled area should be adequately ventilated to minimize air contamination. Mechanical ventilation may also be used in order to provide comfort to the employees although it is not normal to maintain an air pressure negative to atmospheric air. Filtration of extracted air may be necessary particularly where there is risk to the wider environment;
- (iv) In case of risk of harm from total loss of the containment facility, the designed of the facility should be such that it contains the spillage of the entire contents of the fermenters. The containment facility may be designed to include the building of enlarge drainage channels and/or drainage to the kill tank. The method of containment employed should also allow for inactivation of the GMMs;

**(b) Fermentation Methods, Equipment and Utilities**

- (v) Viable GMMs should be contained in a closed system which includes physical barriers to separate them from the population and wider environment. The design of the equipment to be used in the facility should be appropriate to the risk assessment;
- (vi) Pipe works and stop valves installed should be designed in such a way to avoid leakage and ensure ease of cleaning. Connection of services to equipments in the facility should consider prevention of back-flow. A differential pressure system will help. If backflow contamination emerges as a problem, steam locks and bleed systems should be considered. In order to minimize the risk of accidental release of GMMs materials, it is recommended to undertake the addition of materials to a closed system and transfer of viable GMMs to another closed system. All potentially contaminated liquids should be transported in closed piping;
- (vii) Inoculation of seed vessels can be done by direct injection utilizing sterile needles/septum techniques or by utilizing a close system;

- (viii) Static seals to be used on equipment should be designed to minimize accidental release of GMMs. The types of seals recommended for containment level B 2 are (i) single “O” ring seals, (ii) flat gasket (iii) diary type seal couplings and (iv) sanitary couplings with gaskets. The list of seals is not exhaustive and therefore other alternatives can be used if appropriate;
- (ix) It will be necessary to assess the operating pressure system to be used and their associated risk of GMM release. The design of the pressure relief system needs to be carefully considered. Recommended methods can include chains of venting vessels;
- (x) Bulk culture fluids should not be removed from the closed system unless the viable GMMs are inactivated by validated methods. Utilization of chemical or physical methods is acceptable;
- (c) **Maintenance**
- (xi) Equipment and control measures should be tested and monitored regularly. The fermenters should be tested for leakages, especially during commissioning and before every operation and after a major engineering change or undertaking of maintenance work. Testing for leakages can be performed utilizing compressed air, vacuum or tracer gases and water. In order to minimize exposure of maintenance personnel, only trained production staff should be used for this purpose;
- (d) **Management Systems**
- (xii) Workers should be adequately trained in both routine and emergency procedures. Written operating instructions, including emergency plans and spillage policy should be made available to all personnel working in the containment facility;
- (xiii) Access to the containment facility should be restricted to nominated personnel if so indicated by the risk assessment. Entry to the containment facility can be aided by a pass system, dress code, card keys, digital locks or similar methods;
- (xiv) Laboratory coats or gowns (preferably with side or back fasteners) should be provided and worn at all times in the laboratory. As a practice, coats should be removed before washing of hands prior to leaving the laboratory. Importantly, sufficient number of pegs should be provided in the laboratory suit to allow for only a coat/gown per peg. Coats/gowns should be changed on a regular basis and must be changed immediately when contamination takes place;
- (xv) Hand washing facilities, ideally with foot or elbow operated taps should be provided for personnel together with disinfectant soap. Emergency showers and eye wash facilities will be useful;
- (xvi) Biohazard signs should be displayed at the entrances and other suitable locations for the benefit of visitors;
- (xvii) Care should be taken to minimize the release of GMMs into the work place during sample collection. Samples should be collected using aseptic techniques. This will often involve sterilizing the sampling connections. The receiving container should be designed to minimize the release of aerosols;

(e) **Waste Management and Gas Emissions**

- (xviii) Infected waste material and effluent containing viable GMMs should be inactivated by validated methods (use of separate kill tanks) prior to final disposal. Chemical or physical methods of GMMs inactivation can be used but for chemical treatment, the constituents of the waste should be considered. However, all waste disposal should be done in accordance with existing legislation or acceptable international standards and in consultation with the Biological Safety Officer and the National Environment Agency (NEA) at the very early stages;
- (xix) Exhaust gases should be treated so as to minimize accidental release of GMMs. Several methods of treating gases are available but the most efficient method or combination of methods should be used to achieve the desired results;

(d) **Accidents and Emergencies**

- (xx) If the risk assessment indicates that in the case of unforeseeable accidents, the health and safety of persons outside the facility may be affected or their exist risk to the wider environment, there will a need to develop emergency plans. Not withstanding the requirement for a formal plan, it is good practice to develop procedures to deal with spillage, and;
- (xxi) Many activities under containment level B2 may require monitoring, depending on the provisions of the risk assessment. Where there is risk to human health or the environment from organisms outside the close system, monitoring for viable process organisms should be carried out.

(iii)**GNBSA Containment Level B3**

(a) **Building Design/Controlled Measures**

- (i) The risk assessment will usually indicate that activities to be performed under containment level B3 should be undertaken in a controlled environment. The facility should be separated from the offices, laboratories and other facilities;
- (ii) Good standard of hygiene and sanitary conditions should always be maintained and this can be facilitated by a well designed building. The building which should be of normal industrial specifications with sealed impervious floors and standard industrial walls. Floors can be constructed with non-porous concrete to facilitate its cleaning. Walls and ceilings should be covered with resin bonded fiber;
- (iii) The risk assessment will indicate continuous air flow when work is in progress as a requirement and in such cases the controlled area should be adequately ventilated to minimize air contamination. Mechanical ventilation may also be used in order to provide comfort to the employees although it is not normal to maintain an air pressure negative to atmospheric air. Filtration of extracted air may be necessary particularly where there is risk to the wider environment;

(iv) In case of risk of total loss of the containment facility, the designed of the facility should be such that it contains spillage of the entire contents of the fermenters. The containment facility should provide for large drainage channels and the method of containment employed should also allow for inactivation of the GMMs;

(b) **Fermentation Methods, Equipment and Utilities**

(v) Viable GMMs should be contained in a closed system which includes physical barriers to separate them from the population and wider environment. The design of the equipment to be used in the facility should be appropriate to the risk assessment;

(vi) Pipe works and stop valves installed should be designed in such a way to avoid leakage and ensure ease of cleaning. Connection of services to equipments in the facility should consider prevention of back-flow. A differential pressure system will help. If backflow contamination emerges as a problem, steam locks and bleed systems should be considered. All pipe works should welded wherever practicable;

(vii) Inoculation of seed vessels should be performed so as to prevent accidental release. Direct injection utilizing sterile needles/septum techniques is not recommended for containment level B3;

(viii) Doubled faced mechanical Agitator seals are recommended for used on all equipments, ideally with the condensate temperature monitored and equipped with an alarm system;

(ix) It will be necessary to assess the operating pressure system to be used and their associated risk of GMM release. The design of the pressure relief system needs to be carefully considered. Recommended methods can include chains of venting vessels;

(x) Bulk culture fluids should not be removed from the closed system unless the viable GMMs are inactivated by validated methods. Utilization of chemical or physical methods is acceptable;

(xi) Equipment and control measures should be tested and monitored regularly. The fermenters should be leak tested, especially during commissioning and before every operation and after a major engineering change or maintenance. Testing for leakages can be performed utilizing halogens. In order to minimize exposure of maintenance personnel, only trained production staff should be used for this purpose;

(c) **Management Systems and Work Practices**

(xii) Workers should be adequately trained in both routine and emergency procedures. Written operating instructions, including emergency plans and spillage policy should be made available to all personnel working in the containment facility;

- (xiii) Access to the containment facility should be restricted to nominated personnel only. Entry to the containment facility can be aided by a pass system, dress code, card keys, digital locks or similar methods;
- (xiv) Hand washing facilities, ideally with foot or elbow operated taps should be provided for personnel together with disinfectant soap. Emergency showers and eye wash facilities will be useful;
- (xv) Laboratory coats or gowns (preferably with side or back fasteners) should be provided and worn at all times in the laboratory. As a practice, coats should be removed before washing of hands prior to leaving the laboratory. Importantly, sufficient number of pegs should be provided in the laboratory suit to allow for only a coat/gown per peg. Coats/gowns should be changed on a regular basis and must be changed immediately when contamination takes place;
- (xvi) Biohazard signs should be displayed at the entrances and other suitable locations for the benefit of visitors;
- (xvii) Consideration should be given to the transferring of data from the containment area through electronic means;
- (xviii) Care should be taken to prevent the release of GMMs into the work place during sample collection. Samples should be collected using aseptic techniques. This will often involve sterilizing the sampling connections. The receiving container should be designed to minimize the release of aerosols;

(d) **Waste Management and Gas Emissions**

- (xix) Infected waste material and effluent containing viable GMMs should be inactivated by validated methods (use of separate kill tanks) prior to final disposal. Chemical or physical methods of GMMs inactivation can be used but for chemical treatment, the constituents of the waste should be considered. However, all waste disposal should be done in accordance with existing legislation or acceptable international standards and in consultation with the Biological Safety Officer and the National Environment Agency (NEA) at the very early stages;
- (xx) Exhaust gases should be treated so as to minimize accidental release. Several methods of treating gases are available for treatment of gases but the most efficient method or combination methods should be used to achieve the desired results;

(e) **Accidents and Emergencies**

- (xxi) It will normally be expected that the health and safety of persons outside the facility will be affected and risk to the wider environment should be expected. Emergency plans **Must** therefore be developed. Notwithstanding the requirement for the development of a formal plan, it is good practice to develop procedures to deal with spillage;
- (xxii) All accidents, spillages and exposure to infective material need to be immediately recorded and reported to the Biological Safety Officer and the NEA, and;

- (xxiii) Many activities under containment level B3 will require monitoring for risk to human health and the environment from process organisms from containment level B3. Monitoring for viable process organisms should be carried out in and around the facility.

(iv) **GNBSA Containment Level B 4**

Large scale containment level B 4 facilities are very rare and extremely specialized. The guidelines provided in this section are only an outline of the regulatory requirement and potential users will be required to seek advised from GNBSA at an early stage if the need to construct such facilities exist. The section is provided to sensitize the general population that such levels of activities do exist.

(a) **Building Design/Controlled Measures**

- (i) The risk assessment will usually indicate that activities should be undertaken within a purpose built controlled facility. The facility should be physically separated from all other facilities;
- (ii) Scrupulous levels of Good standards of hygiene and sanitary conditions should always be maintained and this need be considered in the design of the facility;
- (iii) The risk assessment will indicate continuous air flow within the control areas and the controlled areas need to be well ventilated to minimize air contamination. Mechanical ventilation may also be used in order to provide comfort to the employees although it is not normal to maintain an air pressure negative to atmospheric air;
- (iv) In case of risk of total loss of the containment facility, the designed of the facility should be such that it contains spillage of the entire contents of the fermenters. The containment facility should provide for large drainage channels and the method of containment employed should also allow for inactivation of the GMMs;

- (b) **Fermentation Methods, Equipment and Utilities**
- (v) Viable GMMs should be contained in a fully closed system which includes physical barriers to separate them from the population and wider environment. The design of the equipment to be used in the facility should be appropriate to the risk of assessment;
  - (vi) Pipe works and stop valves installed should be designed in such a way to avoid leakage and ensure ease of cleaning. Connection of services to equipments in the facility should consider prevention of back-flow. A differential pressure system will help. If backflow contamination emerges as a problem, steam locks and bleed systems should be considered. all pipe works should be properly welded wherever practicable;
  - (vii) Inoculation of seed vessels should be performed so as to prevent accidental release. Direct injection utilizing sterile needles/septum techniques is not recommended for containment level B 4;
  - (viii) Doubled faced mechanical Agitator seals are recommended for used on all equipments, ideally with the condensate temperature monitored and equipped with an alarm system;
  - (ix) It will be necessary to assess the operating pressure system to be used and their associated risk of GMM release. The design of the pressure relief system needs to be carefully considered. Recommended methods can include chains of venting vessels;
  - (x) The controlled area must be sealable to permit fumigation;
  - (xi) Bulk culture fluids should not be removed from the closed system unless the viable GMMs are inactivated by validated methods;
  - (xii) Equipment and control measures should be tested and monitored regularly. The fermenters should be tested for leakages, especially during commissioning and before every operation and after a major engineering change or maintenance. Testing for leakages can be performed utilizing halogens. In order to minimize exposure of maintenance personnel, only trained production staff should be used for this purpose;
- (d) **Management Systems and Work Practices**
- (xiii) Workers should be adequately trained in both routine and emergency procedures. Written operating instructions, including emergency plans and spillage policy should be made available to all personnel working in the containment facility;
  - (xiv) Access to the containment facility should be restricted to nominated personnel only. Entry to the containment facility can be aided by a pass system, dress code, card keys, digital locks or similar methods;
  - (xv) Decontamination and washing facilities must be provided for personnel together with disinfectant soap. Emergency showers and eye wash facilities will be useful. Personnel must shower before leaving the control area. Effluent from the sink and showers must be collected and inactivated before discharge;

- (xvi) Laboratory coats or gowns (preferably with side or back fasteners) should be provided and worn at all times in the laboratory. As a practice, coats should be removed before washing of hands prior to leaving the laboratory. Importantly, sufficient number of pegs should be provided in the laboratory suit to allow for only a coat/gown per peg. Coats/gowns should be changed on a regular basis and must be changed immediately when contamination takes place;
- (xvii) Biohazard signs should be displayed at the entrances and other suitable locations for the benefit of visitors;
- (xviii) Consideration should be given to the transferring of data from the containment area through electronic means;
- (xix) Care should be taken to prevent the release of GMMs into the work place during sample collection. Samples should be collected using aseptic techniques. This will often involve sterilizing the sampling connections. The receiving container should be designed to minimize the release of aerosols
- (xx) Infected waste material and effluent containing viable GMMs should be inactivated by validated methods (use of separate kill tanks) prior to final disposal. However, all waste disposal should be done in accordance with existing legislation or acceptable international standards and in consultation with the Biological Safety Officer and the National Environment Agency (NEA) at the very early stages;
- (xxi) Exhaust gases must be HEPA treated to prevent accidental release;
- (xxii) It will normally be expected that the health and safety of persons outside the facility will be affected and risk to the wider environment should be expected. Emergency plans **Must** therefore be developed. Notwithstanding the requirement for a formal plan, it is good practice to develop procedures to deal with spillage;

(e) **Accidents and Emergencies**

- (xxiii) All accidents, spills and exposure to infective material need to be immediately recorded and reported to the Biological Safety Officer and the NEA, and;
- (xxiv) All activities under containment level B4 will require monitoring for risk to human health or the environment from process organisms from containment level B4. Monitoring for viable process organisms should be carried out in and around the facility.

## 1.2 Summary of Containment and Control Measures for Small Scale Activities

Table 1 specified below, summarizes the system of selection of containment and control measures for small scale activities which have been found suitable and should be used in conjunction with (a) **Regulatory requirements for Determining GMO containment and control measures/General Guidance** and (b) **Selection of Containment and Control measures**. The containment and control measures for a specific activity should be selected based on the risk assessment. It is acceptable to select containment and control measures from more than one containment level for a given activity if so required by the risk assessment. The provisions contained in the table below apply to the preparation of seed cultures and for process control laboratories associated with large scale activities. The containment and control measures are designed for organisms which constitute a health hazard or may cause disease in both human beings and animals or living components of the environment. The measures detailed in the table are equivalent to those required for work with biological agents under the **Control of Substances Hazardous to Health** in the United Kingdom (1994). Other containment and control measures for the EU, USA etc are also available but the UK requirements are adequate for establishing and implementing the Gambia Biosafety framework.

**Table 1: Summary of Containment and Control Measures for Small Scale Activities**

Containment and Control measures	Containment Level 1	Containment Level 2	Containment Level 3	Containment Level 4
<b>Building/Physical Measures</b>				
Provision of separated workplace from other activities in the same building.	No	No	Yes	Yes
Maintenance of air pressure negative to atmospheric air.	No	No, unless the building is mechanically ventilated	Yes	Yes
Input and extract air to the facility to be filtered using HEPA system or equivalent.	No	No	Yes for extract air	Yes for extract air
Easy to clean work bench and table surfaces impervious to water and resistant to acids, alkalis, solvents and disinfectants.	Yes for benches	Yes for benches	Yes for benches and floor (include walls for animal containment)	Yes for benches and floor (include walls for animal containment).
Provide for observation window in order that occupants can be seen.	Yes for benches	Yes for benches	Yes for extract air	Yes for extract air
Provide efficient vector control for insects and rodents.	No	Yes for animal containment	Yes for animal containment	Yes
Containment facility to be sealable in order to facilitate fumigation.	No	No	Yes	Yes
Ensure that effluents from sinks and showers are collected and inactivated before disposal.	No	No	Optional	Yes
<b>Work Practice/Measures</b>				
Posting of <b>Biohazard</b> signs and level of work to be posted for benefit of visitors.	No	Optional	Yes	Yes

Access restricted to authorized persons only	No	Yes	Yes	Yes
Personnel trained in both routine operations and emergencies.	Yes	Yes	Yes	Yes
Ensure that laboratory doors are closed when work is in progress.	Optional	Optional	Yes and keep door securely locked when unoccupied	Yes and ensure that door is always locked.
Provision personal protective equipment	Yes	Yes	Yes	Yes
Provision protective clothing	Optional	Optional	Optional	Yes
Ensure that respiratory are available	No	No	No	Yes
Ensure that protective clothing is decontaminated before laundering.	No	Optional	Yes	Yes
Smoking, eating and drinking strictly prohibited in workplace at all times.	Yes	Yes	Yes	Yes
Laboratory to contain and use only its own equipment.	No	No	Yes as much as possible	Yes
Ensure that equipment and control measures are tested and properly maintained.	Yes	Yes	Yes	Yes
Viable material including infected animals to be handled in suitable safety cabinets.	No	Yes if aerosol is produced	Yes if aerosol is produced	Yes, class III cabinets
Monitoring for the relevant organisms outside the containment facility.	Optional	Optional	Yes	Yes
Ensure the storage of GMMs.	Yes	Yes	Yes	Yes, use secure storage containers
Contaminated waste materials to be inactivated prior to disposal.	Optional	Yes, use validated mechanisms	Yes, by validated chemical or physical means	Yes, use validated physical or chemical means.
Provision of Autoclave facilities in the laboratory.	Optional	Optional	Optional	Yes, use only double ended autoclave
Availability of incinerator for the rapid incineration of animal carcasses	Optional	Should be accessible	Should be accessible	Yes, should be available on site.
Provision of adequate decontamination and washing facilities.	Yes	Yes	Yes	Yes
Ensure that personnel shower before leaving laboratory facility.	No	No	Optional	Yes

“Optional” in table 1 indicates that the requirement is based on the risk assessment and therefore the option must be enforced.

### 1.3 Summary of Containment and Control Measures for Large-Scale Activities

Table 2 specified below like table 1, summarizes the system of selection of containment and control measures for large scale activities which have been found suitable and should be used in conjunction with (a) **the Selection of Containment and Control measures** and (b) **Regulatory requirements for Determining GMO containment and control measures/General Guidance**. The containment and control measures for a specific activity should be selected based on the risk assessment. It is acceptable to select containment and

control measures from more than one containment level for a given activity if so required by the risk assessment.

**Table 2: Summary of Containment and Control Measures for Large-Scale Activities**

Containment and Control Measures	Containment Level B1	Containment Level B2	Containment Level B3	Containment Level B4
<b>Building Design</b>				
Provision of a closed system located within a controlled area.	Not applicable	Optional	Optional	Yes and specifically built
Controlled area ventilated to minimize air contamination.	No	Optional	Optional	Yes
Controlled area at air pressure negative to atmosphere.	No	No	Optional	Yes
Input and extract air to be provided to controlled area using HEPA filters.	No	No	Optional	Yes.
Ensure that controlled area is sealable to permit fumigation as and when required.	No	No	Optional	Yes
Ensure that controlled area is designed to contain spillage of entire contents of closed system.	No	Optional	Yes	Yes
<b>Fermentation Methods, Equipments and Utilities</b>				
Viable micro-organisms in closed system designed to separate them from environment.	No	Yes	Yes	Yes
Addition of materials to close system and transfer of micro-organisms.	Not applicable	Minimize release	Minimize release	Prevent release
Equipment seals designed to prevent spillage	Minimize release	Minimize release	Prevent release	Prevent release
Bulk culture fluids not to be removed from closed system unless the viable organisms have been inactivated.	Not applicable	Inactivated by validated means	Inactivate by validated physical or chemical means	Inactivated by validated physical or chemical means
<b>Maintenance</b>				
Ensure that equipments and control measures are regularly tested and maintained.	Yes	Yes	Yes	Yes
<b>Management Systems and Work Practices</b>				
Personnel trained in both routine operations and emergencies.	Yes	Yes	Yes	Yes
Access restricted to nominated personnel only.	No	Optional	Yes	Yes
Provision of adequate decontamination and washing facilities for personnel.	Optional	Yes	Yes	Yes
Personnel shower before leaving controlled area.	No	No	Optional	Yes
Provision personal protective clothing	No	No	Optional	Yes
Biohazard signs posted to warn unauthorized persons from entry into controlled area.	No	Optional	Yes	Yes
Ensure that personnel wear protective clothing.	Yes	Yes	Yes	Yes, a complete change is required
Ensure that protective clothing is decontaminated before laundering.	No	Optional	Yes	Yes
Smoking, eating and drinking strictly prohibited in workplace at all times.	Yes	Yes	Yes	Yes

### Sampling Procedure

Collect samples in work area to determine release or spillage of GMMs.	Minimize release	Minimize release	Prevent release	Prevent release
Undertake sampling using aseptic technique	No	Optional	Yes	Yes

### Waste handling and Gas Release

Ensure that equipment and control measures are tested and properly maintained.	Yes	Yes	Yes	Yes
Effluents from sinks and showers are collected and inactivated before disposal.	No	No	Optional	Yes
Effluent treatment before final disposal	Optional	Inactivated by validated means	Inactivated by validated physical or chemical means	Inactivated by validated physical means.
Exhaust gases from closed systems treated to prevent release into the atmosphere	Not applicable	Minimize release	Prevent release	Prevent release.

### Accidents and Emergency Plans

Preparation of emergency plans	No 1	Optional	Yes	Yes
Development of procedures for spillage of GMMs in controlled area.	Optional	Yes	Yes	Yes

### Monitoring

Monitoring for process organisms outside primary containment area	Optional	Yes	Yes	Yes
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“Optional” is indicative that the requirement is based on the provisions contained in the risk assessment.

## 1.4 Containment and Control Measures for Work with Naked Oncogenic DNA

The guidelines outlined in this section are designed to provide specific control requirements that could apply to work with oncogenic sequences which are handled as naked DNA preparations. While no precise definition of oncogenes exists, but genes known to be involved in the generation of tumors in human beings and animals may form the basis of an appropriate definition. However, caution needs to be exercised since other genes exist that generate phenotypes which can be involved in tumorigenesis. Similarly, potentially oncogenic sequences handled as preparations of naked DNA or in viral vectors with a human host range may be defined as carcinogens. Also there exist some difficulties in the exact definition of carcinogens and it is therefore recommended to adopt a precautionary approach where doubts exist on the exact status or definition of Oncogenic DNA sequences as carcinogens.

As part of the overall recommendations, oncogenes present in GMOs should be assessed and controlled as detailed under 2.5 – 2.5.9 (**Risk Assessment of GMOs other than Eukaryotic viruses**) and 2.6 – 2.6.13 (**Risk Assessment of GM modified Human and animal Viruses and Viral Vectors**). The guidelines contained in this section should not prevent the assignment of a specific experiment to a higher standard of containment where this is appropriate.

The likely routes of transmission of naked oncogenic sequences to laboratory personnel will primarily be through inoculation or entry through broken skin. Other routes of transmission such as inhalation, ingestion and splashes to the face can be discounted as possible routes of transmission which will likely lead to tumorigenesis. It is imperative for the Genetic Modification Safety Committee to consider all risks to personnel in handling of oncogenes and related DNA sequences as naked DNA, especially if they are linked in a recombinant to strong promoters or enhancer sequences that function in mammalian cells. The GMSC should ensure that laboratory based rules and regulations provide effective guidance on the maintenance of laboratory discipline and on avoiding accidental inoculation of employees.

Laboratory personnel with unprotected skin lesions on their hands or forearms should not be expected to work with oncogenes and related sequences without adequately consulting and subsequently obtaining the approval of the BSO. Personnel with such conditions should be stopped from handling oncogenes and related sequences until such time that they are properly healed. Alternatively, the use of personal protective clothing such as gloves and laboratory gowns may be adequate to prevent exposure. In some extreme cases, medical advice may be necessary.

## **1.5 COSHH Containment and Control Measures**

In general, it is recommended that exposure to substances hazardous to human and animal health (including exposure to carcinogens) is prevented at all cost or where this not reasonably possible to prevent exposure, the provisions of control of substances hazardous to health should provide for adequate control. In instances where the oncogenic DNA is positively a carcinogen and it is not possible to prevent exposure, the following control measures must be applied:

- 3.11.1 ensure the total enclosure and handling systems of the oncogenic DNA in order to avoid control exposure;
- 3.11.2 minimize the generation or suppress and contain spillages and leakages and control dust, fumes and vapors emanating from carcinogens;
- 3.11.3 limit the quantities of carcinogens in the workplace;
- 3.11.4 limit the number of personnel exposed to carcinogens to the barest minimum;
- 3.11.5 ensure that all personnel desist from eating, drinking or smoking in the laboratory;
- 3.11.6 ensure that hygienic conditions are always maintained in the laboratory;
- 3.11.7 ensure that areas that are contaminated are identified through warning signs, and;
- 3.11.8 ensure that oncogenic sequences and all other contaminated materials are safely stored, handled and disposed.

Many of the measures detailed above are part of normal laboratory practice and requirements for work with GMOs or biological agents. The uncertainty surrounding the hazards of most potentially oncogenic sequences and considering the small quantities that are generally used prevention of exposure or total enclosure will rarely be necessary.

In addition, the measures detailed below should be used in conjunction with the selection of containment and control measures discussed in other sections:

- (i) It is emphasized that good laboratory techniques be employed in working with carcinogens. All laboratory workers should be adequately trained in good laboratory techniques as part of their re-orientation prior to working with oncogenic DNA sequences and should be fully aware of the potential hazards of such work activities;
- (ii) Access to laboratory or containment facilities where naked DNA sequences is handled should be strictly limited to only authorized personnel and designated workers;
- (iii) Work areas (work benches and table tops) for oncogenic DNA sequences should be properly identified. All designated workers and those likely to be exposed to oncogenic DNA sequences should be required to strictly follow laboratory based rules and regulations;
- (iv) Appropriate hand gloves should be worn for all work with naked oncogenic DNA sequences. Gloves which should be changed regularly should be selected taking into account their resistance to the chemicals in use. The use of hand gloves should not prevent dressing of cuts with appropriate sanitary bandages;
- (v) Sharp items should be avoided for work with naked oncogenic DNA sequences except where necessary. Glassware should not be used in instances where plastic alternatives are available;
- (vi) All experimental procedures involving naked oncogenic DNA should be performed to minimize aerosol production. Procedures which are likely to generate aerosols such as use of blenders, vigorous shaking and mixing must be performed under strict engineering controls. The suitability of the system should be decided after the risk assessment, and;
- (vii) Where there may be an additional microbiological hazard, a microbiological safety cabinet should be used.

## **1.6 Fumigation Process**

Contamination of laboratories, animal containment facilities and safety cabinets require decontamination when spillages of infected materials occur or facilities are being used for the first time and/or during maintenance activities. Fumigation should be carried out as part of a planned exercise using appropriate fumigation techniques. Only trained personnel working to an agreed plan and using standard methods known to be effective should be used.

In carrying out fumigation operations, it is recommended to use formaldehyde which has been known to be effective for many years as a biocidal agent. As commonly used fumigant, the usual source is formalin, readily available as 40% solution of formaldehyde vapor in water. There exist a number of methods for generating formaldehyde vapor but in order to avoid violent reactions, it is recommended to use commercially available formaldehyde generating kits or purpose made vaporizing units (safety cabinets).

In order for formaldehyde to have maximum effect, it must be able to penetrate and dissolve at adequate concentration in moisture films within the immediate surrounding of the organism to be inactivated. Pre-cleaning is therefore helpful if it can be carried out without compromising safety. Water vapor generated in the process of dispersing formaldehyde provides the essential optimum level of relative humidity.

Prior to the changing of filters in **microbiological safety cabinets** or before any maintenance activity is undertaken, it should be preceded by fumigation of the cabinets, particularly after large spillage of infectious materials. Upon successful completion of the fumigation process, the fumigant should be exhausted to the atmosphere by switching on the electric fan and allowing room air to enter the cabinet. Employees and other unauthorized personnel should not be allowed in the vicinity of the exhaust outlets and also ensure that the exhaust air does not enter adjacent windows and ventilation systems. Finally, discarded filter units should be autoclaved and bagged before disposal.

The BSO and trained personnel assigned to fumigate **laboratory room** or **animal containment facilities** should ensure that the facilities are adequately sealed to avoid escape of fumigants. Certain chemicals such as hydrochloric acids, chlorinated disinfectants etc should be removed before fumigating with formaldehyde. Fumigators should test the effectiveness of their fumigation and six hours after fumigation, the fumigant should be extracted through the air handling system. It is also expected that subsequent to the extraction of the fumigant, the facility should be tested for residual vapor prior to entry by personnel. Personnel should not be allowed entry into an area or room after a major spillage of micro-organisms due to the risk of infection from suspended air. Also personnel should not be allowed into the facility after fumigation except in dire emergencies, in which case breathing apparatus which provide air from an independent source should be used. Respirators are not recommended for use in concentration of formaldehyde vapor generated through the fumigation process.