THE SCOPE OF BIOSAFETY AND BIOSECURITY IN UGANDA

Policy Recommendations for the Control of Associated Risks

A Consensus Study Report

Uganda National Academy of Sciences

Science Advisors to the Nation

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UGANDA NATIONAL ACADEMY OF SCIENCES

Uganda National Academy of Sciences (UNAS) is an autonomous body that brings together a diverse group of scientists from the physical, biological, social and behavioural sciences to work together in an inter-disciplinary and trans-disciplinary manner. The main goal of UNAS is to promote excellence in science by offering independent evidence-based advice for the prosperity of Uganda. UNAS was granted a Charter to operate as the National Academy of Uganda by H.E. the President of the Republic of Uganda in January 2009.

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This report has been reviewed in draft form by independent reviewers chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the Uganda National Academy of Sciences (UNAS) Council. The purpose of this independent review is to provide candid and critical comments to assist UNAS in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

The Uganda National Academy of Sciences thanks the following individuals for their participation in the review process:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Patrick Rubaihayo, Professor Emeritus, Department of Crop Science, Faculty of Agriculture, Makerere University, who was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with individual paper authors and the authoring committee.

Preface

UGANDA NATIONAL ACADEMY OF SCIENCES

The mission of the Uganda National Academy of Sciences (UNAS) is to contribute towards improving the prosperity and welfare of the people of Uganda by promoting, generating, sharing and utilizing scientific knowledge and information and to give independent, evidence-based advice to government and society. The mission is intended to advance the ability of Uganda to address its most serious national development challenges by (1) engaging in a series of scientific activities designed to elucidate potential evidence-based solutions to pressing national and regional health and other concerns; (2) enhancing the general capacity of UNAS to provide relevant and useful scientific policy advice; and (3) building Uganda's appreciation of and demand for advice from the Academy.

Like many other academies of science, UNAS is an autonomous body that brings together a diverse group of scientists from the health, agricultural, earth, engineering, physical, biological, social and behavioural sciences. These scientists work together in an interdisciplinary and trans-disciplinary manner to achieve their main goal of promoting excellence in science by offering independent, evidence-based advice for the prosperity of Uganda. The success of any academy lies in the strength and expertise of its

membership and its ability to mobilise scientific experts to continually advise policymakers.

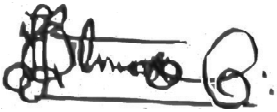
Through various convening activities in recent years (including the workshop on "*Establishing and Promoting Good Laboratory Practice and Standards for Running Safe, Secure and Sustainable Laboratories in Sub-Saharan Africa"* (2009), it became apparent to the Academy's stakeholders that there was lack of consensus regarding the meaning and scope of biosafety and biosecurity in Uganda, a problem that needed to be addressed in order to provide guidance to both policymakers and legislators in Uganda in light of the absence of a requisite policy, legal and regulatory framework for the country. The Academy thus embarked on this consensus study, responding to a national need, with a view to providing evidence-based advice to government and the general public in line with her mission.

This report consists of the Consensus Study Committee's conclusions and recommendations along with supporting text and references.

Acknowledgements

The Uganda National Academy of Sciences and the Committee on "Assessing the Current State of Knowledge Pertaining to the Meaning and Scope of Biosafety and Biosecurity in the Context of Uganda" wish to express their warmest appreciation to the individuals and organisations who gave valuable time to provide information and advice to the Committee through their participation in the framing of the study topic through to the open session workshop of the study.

The Committee is indebted to the UNAS staff (in particular Franklin Muyonjo – who directed the study) for the part they played in the production of this study report. UNAS gratefully acknowledges the sponsors of this study, the US National Academies (USNAS), through the African Science Academy Development Initiative (ASADI); the Programme on Biosafety Systems (PBS) in Uganda (in particular Dr Theresa Sengooba) and the US Department of State (in particular Dr Andrew Hebbeler and Dr Elizabeth Cameron). Special thanks are also extended to the USNAS staff (in especially Patricia Cuff and Christian Acemah) – for having worked closely with the UNAS staff during the course of the study period) and to the reviewers who volunteered their time to provide candid and critical comments to ensure that the report is accurate, effective, and credible.



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Chair, Committee on Assessing the Current State of Knowledge Pertaining to the Meaning and Scope of Biosafety and Biosecurity in the Context of Uganda

Professor Paul Edward Mugambi,

President, Uganda National Academy of Sciences

List of Acronyms

AIDS	Acquired Immune Deficiency Syndrome
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety Level
BTWC	Biological and Toxin Weapons Convention
BWC	Biological Weapons Convention
CDC	Centres for Disease Control and Prevention
DNA	Deoxyribonucleic Acid
EU	European Union
FAO	Food and Agricultural Organisation
GMO	Genetically Modified Organism
HIV	Human Immunodeficiency Virus
IDI/MU JHU	Infectious Diseases Institute / Makerere University-John Hopkins University
JCRC	Joint Clinical Research Centre
KARI	Kawanda Agricultural Research Institute
LMO	Living Modified Organisms
MRC	Medical Research Council
MUWRP	Makerere University Walter Reed Project
NARO	National Agricultural Research Organisation
NIH	National Institute of Health
NIM	National Implementation Measures
NRC	National Research Council
NSAR	The National Select Agents Registry
OAU	Organisation for African Unity

OECD	Organisation for Economic Co-operation and Development
PBS	Programme on Biosafety Systems
SARS	Severe Acute Respiratory Syndrome
TB	Tuberculosis
UK	United Kingdom
UNAS	Uganda National Academy of Sciences
UNBS	Uganda National Bureau of Standards
UNCST	Uganda National Council for Science, and Technology
UNSC	United Nations Security Council
UVRI	Uganda Virus Research Institute
VBM	Valuable Biological Materials
VERTIC	Verification Research, Training and Information Centre
WHO	World Health Organization

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Introduction

The conclusions and recommendations in this report are the Committee's response to their charge as reflected in the Statement of Task. The Committee was asked to review and assess the current state of knowledge pertaining to the meaning and scope of biosafety and biosecurity with a view to informing both policymakers and legislators in Uganda as they attempt to come up with a pertinent national policy and regulatory framework. After listening to testimony as provided by presenters in the open session (see Appendix B), the Committee deliberated in closed session for two days. Using the testimony presented, published literature and their own expertise, the Committee reached conclusions and made recommendations that provide a clearer picture of how Cabinet and Parliament in Uganda can come up with evidence-based policies and legislation with respect to biosafety and biosecurity.

Defining Biosafety and Biosecurity

There is presently no universal consensus on definitions of biosafety and biosecurity accepted around the world. For some in Africa, the term biosafety refers to genetic engineering applied to agricultural products (crops and animals) for improving the productivity and safety of the food supply and for protecting plant biodiversity and the environment. Others view biosafety as minimizing risks

in order to keep medical and scientific laboratory workers safe from potential harms from the pathogens or organisms they are working with. Still others see biosafety on a continuum with biosecurity, which is aimed at keeping pathogenic organisms in the laboratory and out of the hands of terrorists or persons intending to harm others.

By clarifying the domains and where the work of each laboratory fits in the spectrum of biological risk—the overlap of biosafety and biosecurity—government officials are in a better position to determine the need for government intervention to ensure safety and what type of regulatory framework might be valuable.

The Biotechnology / Biosafety Bill in Uganda

In 2008, the Ugandan Cabinet approved the National Biotechnology and Biosafety Policy that establishes a system whereby the country can benefit from safe applications of modern biotechnology while at the same time assess and address any potential risks from those applications (Government of Uganda, 2008). In 2009, the Uganda National Council for Science and Technology developed the Biotechnology / Biosafety Bill which, among other things, is meant to implement the 2008 policy and minimise and manage any potential risks to the environment, human and animal health that may be associated with genetically modified organisms ("GMOs") (UNCST, 2009). A GMO is an organism where DNA from a different organism has been added in the laboratory using recombinant DNA techniques. The

question many policy makers are asking is whether it is necessary to include biosafety and biosecurity measures for medical and scientific laboratories working with pathogens and infectious agents in this bill. In response to this question, this consensus study was undertaken by the Uganda National Academy of Sciences by convening an expert committee to respond to the following Statement of Task.

Statement of Task

Dialogue on biosafety and biosecuity is currently hindered because these terms often mean different things to different stakeholders, professionals, and scientists. Recognizing this, the Uganda National Academy of Sciences convened a multi-disciplinary, consensus committee to look at definitions of biosafety and biosecurity in different contexts and establish overlaps and areas of agreement among them. The Committee was also asked to outline activities conducted in and out of laboratory and research facilities that fall under the domains of biosafety, biosecurity or both and to include the risks those activities pose to human, animal, plant and/or environmental health. Additionally, the Committee was asked to recommend ways in which the terms biosafety and biosecurity might be expressed in order to optimize communication among different communities that have different understandings of what the terms mean.

Methodology

The Academy convened a seven-member expert committee (and one consultant) to respond to the above statement of task (SOT). Their expertise included agricultural biotechnology and biosafety; biosecurity and biorisk; legal and regulatory systems relating to biotechnology and biosafety and international conventions and protocols; veterinary epidemiology; molecular biology; forensic toxicology and biological defence and national defence; and Ugandan laboratory systems. Such a variety of expertise was intended to bring diverse view points needed to respond to the SOT.

To effect the task entailed in their charge, this consensus study committee came together for one day of open information gathering (where different experts delivered pertinent papers and during which panel discussions relating to biosafety and biosecurity ensued) followed by two days of closed door deliberations. Using the testimony presented (at the information-gathering stage), published literature and their own expertise, the Committee reached ten conclusions and made six recommendations that provide a clearer picture of how Cabinet and Parliament in Uganda can come up with evidence-based policies and legislation with respect to biosafety and biosecurity. Research was then conducted to get supporting literature (text) for these conclusions and recommendations – all of which were later peer-reviewed for accuracy and appropriateness. The result of these efforts is this report.

Committee Conclusion and Recommendations

Conclusion 1

When working in medical and scientific laboratories, the risks are determined by the organism being used and the activity being conducted.

There are four Biosafety Levels, from one to four (see Box 1). The numbers relate to the risks associated with the experimental organisms and necessary precautions to prevent disease. The levels increase in safety and security measures as the dangers associated with the biologicals increase (see biosafety requirements in Table 1).

When discussing either biosafety or biosecurity or both, the importance and value of working with an organism can hardly be over-emphasized. Clinical laboratories, for example, must be able to aid with the diagnosis of infectious diseases. Research on infectious agents and GMOs on the other hand has the critical goal of improving human, animal and plant health.

Conclusion 2

Furthermore, based on the research organism, a number of biosafety and/or biosecurity measures may apply.

When working with biological contaminants, protecting just the worker is oftentimes not enough. Systems must also be in place to protect the environment and the facility from possible contamination (CDC and NIH, 1999). Depending on the type of infectious biological microorganism or laboratory animal, specific containment and safety procedures must be followed.

In Uganda, BSL3 laboratories are located at Uganda Virus Research Institute (UVRI) in Entebbe and at the Makerere University Walter Reed Project (MUWRP) in Mulago, Kampala. UVRI deals with highly pathogenic organisms, HIV culture, ELISPOT assay, virus inhibition assays, viral neutralization assay, and TB culture while MUWRP deals with viral neutralization assay. (Katongole-Mbidde, 2009). There are no BSL-4 laboratories in Uganda.

Box 1
The Four Laboratory Biosafety Levels

Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand washing. Hence the practices, safety equipment and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other laboratories in which work is done with defined and characterised strains of viable microorganisms not known to consistently cause disease in healthy adult humans, animals and plants. What is required, therefore, are minimum decontamination / cleaning procedures.

Biosafety Level 2 applies to clinical, diagnostic, teaching and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity. In such labs, secondary barriers such as hand washing sinks and waste decontamination facilities must be available to reduce potential environmental contamination.

Biosafety Level 3 is concerned with clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a general potential for (but not exclusively) respiratory transmission, and which may cause serious and potentially lethal infection. Such agents or microbes,

however, may have reliable treatments or cures. Here, more emphasis is placed on primary and secondary barriers to protect personnel in contagious areas, the community, and the environment from exposure to potentially infectious aerosols.

Biosafety Level 4 is applicable to work with the most dangerous and/or exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. BSL-4 facilities are specifically constructed to contain these organisms with heightened security and have special air filtration systems, many airlocks, and decontamination systems. At this level the use of a Hazmat suit and a self-contained oxygen supply is mandatory.

Adapted from: CDC and NIH. 2007. BMBL; 5th Ed. US Government Printing Office, Washington, DC.

Table 1. Summary of biosafety requirements

	BIOSAFETY LEVELS			
	1	**2**	**3**	**4**
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
- Inward air flow	No	Desirable	Yes	Yes
- Controlled ventilating system	No	Desirable	Yes	Yes
- HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes

Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	-
Anteroom with shower	No	No	Yes/No[c]	Yes
Effluent treatment	No	No	Yes/ No[c]	Yes
Autoclave:				
- On site	No	Desirable	Yes	Yes
- In laboratory room	No	No	Desirable	Yes
- Double ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

a Environmental and functional isolation from general traffic.
b Dependent on location of exhaust.
c Dependent on agent(s) used in the laboratory.
d For example, window, close-circuit television, two-way communication.

Adapted from: WHO (2004).

Conclusion 3

The greater the risk of the organism to the health or life of humans, plants, or animals, and the environment, the more stringent the biosafety measures and the need to add biosecurity measures.

In medical and scientific laboratories, exposure to infectious agents during experiments is a plausible

source of infection in persons working with the agent (CDC/NIH, 1999). Microorganisms including bacteria, viruses, fungi or parasites pose a health risk to laboratory workers. These organisms vary significantly with regard to virulence, infectious doses, mode of transmission, ability to produce toxins and the availability of preventive and control measures (Custers, 2004; WHO, 2004). Therefore, they have different magnitudes of risk. It is thus important to establish risks based on the type of organism in question and the level of available control measures.

As organisms increase in pathogenicity from low to high risk, the laboratory biosafety level also rises from 1 to 4 as noted in Box 1. According to the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, the laboratory director is specifically and primarily responsible for assessing the risks and appropriately applying the recommended biosafety levels. When information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified. Often an increased volume or a high concentration of agent may require additional containment practices (CDC and NIH, 2007).

Recommendation 1

Uganda should have an accurate inventory of scientific and medical laboratories and the organisms (pathogens and infectious agents) they are working with, and the levels of biosafety and biosecurity in

those particular laboratories. This information is critical to ensuring appropriate biosafety and biosecurity in Uganda. Uganda National Council of Science and Technology (UNCST), in consultation with relevant stakeholders, should be the agency to catalogue the scientific and medical laboratories and the (most dangerous of the) organisms they are working with.

There are more than five hundred medical laboratories in Uganda with a mix of Government, NGO and private laboratories at various levels (Balinandi, 2009). Government and NGO owned laboratories are primarily service delivery oriented and barely require any financial obligation to the beneficiary, but most privately owned laboratories provide services at fees that vary depending on the tests and are primarily for profit.

Overall, laboratory personnel in Uganda are mostly Diploma and Certificate holders, but the number of graduates is gradually increasing. At the same time, techniques in hospital based laboratories are mainly basic, whereas research laboratories are diverse ranging from the basic to state-of-the-art techniques. The organisms handled also vary, from non-pathogenic to highly infectious material (Balinandi, 2009). However in Uganda, the current capacity for research on dangerous pathogenic material and the capability to conduct research on the causative agents of disease that may emerge at a future time is small. Investigations on dangerous pathogenic material are handled at laboratories found at UVRI, MUWRP, Infectious

Diseases Institute (IDI) at Makerere University College of Health Sciences, Joint Clinical Research Centre in Mengo, Kampala, the National Agricultural Research Organisation of the Ministry of Agriculture, Animal Industry and Fisheries, among others. The volume of material handled is unknown. (Katongole-Mbidde, 2009).

Other countries are encouraging formal registers or inventories of labs holding dangerous pathogens. For example in Europe, European Union member states were encouraged to set up formal registers or inventories of laboratories holding live SARS coronavirus (CoV) (Eurosruveillance Weekly, 2004). Similarly, countries in the Pacific Island Region have called for an inventory of laboratories that retain wild poliovirus infectious materials or potentially infectious materials. Those laboratories working with wild polioviruses infectious or potentially infectious materials were asked to immediately implement BSL-2/polio requirements (WHO, 1999). The United States among other nations has also called for such an inventory.

In the US, the National Select Agents Registry (NSAR) Program oversees the activities of possession of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The NSAR currently requires registration of users and facilities including government agencies, universities, research institutions, and commercial entities that possess, use or transfer biological agents and toxins. The US Select Agents List

is a vital reference point in this regard (Rose and O'Connell, 2009).

Conclusion 4

The primary risks from work in medical and scientific laboratories with pathogens or toxins are unintentional exposure/infection of workers, community, and the environment (including plants and animals) to those pathogens or toxins. However, biosecurity measures prevent malicious exposure/infection of workers, community, and the environment (including plants and animals).

The assignment of an agent to risk groups and corresponding biosafety levels, which triggers certain preventive and mitigation measures, is based on a risk assessment (WHO, 2004). The information regarding the type of organisms, mode of transmission, virulence, host range, locally available prevention and treatment options, and capability of personnel, among other criteria, is crucial for development of measures for each research organism.

Conclusion 5

Biosafety guidelines and protocols should always be in place for laboratory work involving any pathogens and toxins.

In the recent past, several laboratory-associated infections have occurred in different parts of the world involving both known and previously unknown agents (CDC and NIH, 1999). This development, coupled with the growing concerns about bioterrorism has led to considerable interest in biosecurity and biosafety matters in recent years. There should therefore always be a combination of standards, practices, safety measures and equipment and facilities in various laboratory settings in an attempt to ensure safety of the employees, the community and the environment. The implementation of these biosafety measures should, however, be based on a risk assessment of the pathogens and toxins being used in the laboratory and the activities the lab is engaged in (CDC and NIH, 1999). Continuous training and retraining in safety would complement the above measures.

Conclusion 6

Based on the results of a survey of existing Ugandan law to implement the Biological Weapons Convention (BWC) and the United Nations Security Council Resolution 1540 (Resolution 1540), the current legal and regulatory framework in Uganda does not comprehensively prevent or prohibit the malicious use of pathogens and toxins, i.e., biological weapons as defined in the BWC.

All States have the obligation to prevent and prohibit the proliferation of biological weapons, either as a State Party to the Biological and Toxin Weapons Convention (BWC); a member of the United Nations, subject to the

provisions of UN Security Council Resolution 1540 (Resolution 1540); or both (See Box 2 for details on the BWC and Resolution 1540). One responsibility arising from this obligation is the need for States to fully implement these instruments through their national laws and regulations. (Spence, Woodward, and Escauriaza, 2009)

The Verification Research, Training and Information Centre (VERTIC) – an independent, non-profit-making, non-governmental organisation, established in 1986 to promote the effective verification and implementation of international arms control and environment agreements – works with countries to implement the BWC and the Resolution 1540. Through their National Implementation Measures (NIM) Programme, VERTIC assists different countries to take a variety of measures to bring their domestic law into conformity with their obligations under international law. These measures may include laws, administrative procedures and regulations. In terms of nuclear, biological and chemical weapons, such measures are important because they enhance national and international security by preventing misuse of materials related to these weapons and by prohibiting any activities involving such weapons throughout a State's territory (Spence, Woodward, and Escauriaza, 2009)

According to VERTIC, national implementation of the BWC and the biological weapons-related provisions of Resolution 1540 can be accomplished by:

1. Understanding the BWC and Resolution 1540 and their requirements;
2. Then implementing the BWC and Resolution 1540 through laws and regulations including:
    a. Adopting criminal prohibitions and penalties, and establishing national and extraterroritorial jurisdiction over these crimes;
    b. Implementing a comprehensive national biosafety and biosecurity framework, including licensing, reporting and inspections, in order to prevent the proliferation of dangerous pathogens that could be weaponised; and
    c. Establishing enforcement measures including policy and response agencies (e.g., a BWC National Authority) and investigative mechanisms; and
3. Taking advantage of existing opportunities:
    a. VERTIC assists states through cost-free legislative analysis and legislative drafting assistance (on-site or remotely)
    b. VERTIC provides States with legislative drafting tools in five languages, including a model law and regulatory guidelines (Spence, Woodward, and Escauriaza, 2009).

With a national legislative framework in place for implementation of the BWC and the biological weapons-related provisions of Resolution 1540, States can investigate, prosecute and punish offences associated

with biological weapons activities committed by non-State actors, including terrorists. It also allows States to monitor and supervise peaceful activities such as domestic research and disease prevention, as well as transfers involving dangerous pathogens and toxins.

Box 2
BWC and Resolution 1540

The BWC prohibits biological warfare and bioterrorism, that is, the intentional use of pathogens or toxins against humans, animals or plants for hostile purposes, as well as any activities involving biological weapons. Biological weapons are defined under the BWC, Article 1, on the basis of *purpose* as:

> (a) biological agents and toxins in types and quantities that have no justification for prophylactic, protective or other peaceful purposes; or
> (b) weapons, equipment and means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

Resolution 1540 was adopted on 28 April 2004 and has been reaffirmed twice. It is a legally binding, Chapter VII Resolution for all UN Member States. The '1540 Committee' promotes and monitors implementation of the Resolution, and seeks to coordinate offers and requests for assistance through its experts.

Under Resolution 1540, States must:

> (a) adopt and enforce national laws to prohibit and prevent non-state actors from manufacturing, acquiring, possessing, developing, transporting, transferring or using nuclear, chemical and biological weapons and their means of delivery; and
> (b) establish a national system (i) to account for and secure items in production, use, storage, or transport; (ii) for physical protection measures; (iii) for effective border controls and law

In 2008, VERTIC assisted the Ugandan government by providing a cost-free legislative analysis of the current laws and regulations related to the implementation of the BWC, including biosecurity measures in Uganda (VERTIC, 2008). Entitled *Survey of Uganda's National Implementing Measures for the 1972 Biological and Toxin Weapons Convention,* this document is meant to assist the government in their national implementation of the BWC and biological weapons-related provisions of Resolution 1540. This document has been provided to the Uganda National Academy of Sciences. The VERTIC survey identifies Ugandan legislation with a bearing on definitions, criminal prohibitions and penalties, jurisdiction, biosafety and biosecurity measures, and enforcement. The applicable legislation is summarized in Tables 2 and 3.

Conclusion 7

The primary risks from agricultural laboratory research with genetically modified organisms (GMOs) are the unauthorised release of the organism to the environment and any potential adverse impacts on agricultural interests and biological diversity. Laboratory containment practices are implemented to prevent such impacts. Theoretically, there is also the risk of the unintended creation of GMOs with excessive levels of toxic compounds with the potential to harm consumers. This risk is controlled at the laboratory level by regulators to make sure that scientists use genes that are known to be safe.

The “contained use” of a GMO means that the research is being conducted in a space enclosed by physical barriers from the outside environment. In practice, this involves work in agricultural and microbiology laboratories, animal houses, plant growth facilities (including growth rooms in buildings and suitable glasshouses) and greenhouses, each of which provides a high level of containment so that the GMO is not released into the environment.

The vast majority of work with GMOs for agricultural purposes in contained use is inherently safe. In each case, there are physical barriers that prevent the escape and persistence of the GMO in the environment. In addition, the researcher usually also uses biological containment strategies that also reduce the chances that the GMO will survive and multiply if it does escape into the environment. Biological containment strategies can include actions such as sterility of the plants or crippling the organism so that it can only grow with specific nutrients not found easily in the outside environment. Thus, safety is built into the experimental design through the physical and biological containment. There could, however, be some exceptions. There is, for example, a possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals (NRC, 2000).

Conclusion 8

There are no known risks of infection to humans and animals from laboratory research involving agricultural GMOs. Biosecurity measures are therefore not foreseen as an issue in this context.

GMOs in food and agriculture have been around long enough for scientists to have some background against which to assess possible infectious risks to humans (Jaffe, 2004). There has been as yet no proven health effect on human life, nor even of a risk pathway for humans to get an infection from GMO plants and animals.

"Biosecurity" usually involves the prevention of the intentional release of a pathogen or infectious agent that can harm humans or animals. For agricultural GMOs, there is no known pathway where such organisms could enter the human body and cause an infectious disease. Therefore, there is no need for biosecurity measures. Biosafety measures alone are sufficient to address possible risks from agricultural research with such organisms (Fresco, 2001).

Conclusion 9

The potential risk level of a confined GMO field trial can be determined by the persistence of the crop and the potential for harm from the introduced trait to the environment. It is at the confined field trial stage, not the laboratory stage, when some potential risks from research with GMOs become more relevant.

The most relevant risks are to the environment and biodiversity.

The regulatory approval of commercial genetically modified crops that will be planted by farmers in the field initially requires small, restricted experimental trials known as confined field trials (Linacre and Cohen, 2006). The purpose of the field trial is to gain information about potential risks of the GMO if it becomes a commercial product in order to conduct the necessary regulatory risk assessment. These small scale experiments provide researchers with important information on environmental interactions and agronomic performance of the crop in a safe and contained manner.

A confined field trial is a restricted environmental release of a GMO under conditions designed to prevent the spread of the organism from the field trial site or its persistence in the environment. It is usually small-scale in size (less than one hectare) and conducted for research purposes in order to evaluate the performance of the organism or to collect data to analyze the safety of the organism. The field trial is considered "confined" because it is conducted under planting conditions that limit the ability for the GE organism to escape from the site. Those conditions might include biological, physical, geographical, temporal, and/or chemical methods of confinement. If there is sufficient confinement, a confined field trial poses relatively little risk to human health or the environment because the chance of escape

into the food supply or persistence into the environment is small (Jaffe, 2006).

The confined field trial will attempt to gather data about whether the commercial GMO will have any environmental risks. For commercial GMO products, there are three types of risks associated with agricultural genetic modification with respect to the environment (see Box 3). Two of these risks – weediness and gene flow – relate to the possibility that crops or their relatives may invade new territory, displace existing plant communities, or reduce species biodiversity. The other type of risk deals with a range of possible consequences due to effects on pests and pathogens. (Cohen, 2005)

Commercial GMO products may also raise potential food safety risks for humans. The potential risks generally relate to "the possibility of introducing new allergens or toxins into food-plant varieties, the possibility of introducing new allergens into pollen, or the possibility that previously unknown protein combinations now being produced in food plants will have unforeseen secondary or pleiotropic effects" (NRC, 2000). Those risks, however, do not apply to confined field trials as the confinement conditions prevent those crops from becoming part of the food supply. Each of those risks, however, is evaluated in the regulatory risk assessment with data that is obtained from research experiments using plants involved in the confined field trials and contained use experiments (Cohen, Komen and Zambrano, 2005; Linacre and Cohen, 2006;).

Box 3

Associated Risks of GMOs To The Environment

Weediness – is the potential for a crop to become established and to persist and spread into new habitats as a result of newly introduced genes. It is an issue when there is scientific evidence that acquisition of the new genes is sufficient to convert a domesticated species into a successful weed.

Gene flow – occurs when new genes are spread by normal out-crossing to wild or weedy relatives of the engineered crop. It becomes an issue if the new trait(s) confers a fitness advantage and becomes stably introgressed into the recipient relative, possibly with negative effects on biodiversity.

Pest and pathogen effects – include a range of possible consequences such as the emergence of target pest populations resistant to an engineered control mechanism. By introducing distinct resistance management schemes, the evolution of insect resistance can be slowed down.

Source: Cohen, Komen and Zambrano, (2005).

Conclusion 10

Some nations have developed control lists and/or risk levels of certain pathogens and toxins that have the potential to be used as biological weapons. Enhanced

biosecurity measures are triggered by any activities involving pathogens and toxins on these control lists, and ideally build on biosafety measures in place for all laboratories.

Activities involving controlled pathogens can be regulated and monitored through controlled agent lists based on threats to public health and safety and national security. Examples of controlled agent lists include the US select agent lists; the Australia Group lists for biological agents, animal and plant pathogens and dual-use technology and equipment; the UK's approved list of biological agents; and the European Union's Community-wide export control lists.

Recommendation 2

Uganda may wish to consider these lists and either adopt one of these as its own or develop its own, taking into account its own national security and public health situation, concerns and strategies.

Lists to control domestic activities or transfers of particularly dangerous pathogens and toxins are discussed in more detail in VERTIC's *Regulatory Guidelines for National Implementation of the 1972 Biological and Toxin Weapons Convention and Biological Weapons-Related Provisions of UNSCR 1540.*[2]

[2] See: http://www.vertic.org/NIM/tools/model_laws/#biological.

Recommendation 3

Many nations have already addressed laboratory biosafety and biosecurity issues. Uganda should study and learn from those experiences and then use aspects of those systems that apply to the situation in the country. This could include adopting risk control levels and associated lists of highly pathogenic organisms and toxins that trigger biosecurity measures, and codes of conduct, guidelines, manuals, and procedures that address biosafety and/or biosecurity.

In Uganda, the above biosafety and biosecurity issues are already in place at the UVRI. Other labs in the country can learn from UVRI. Uganda may also find it useful to refer to model laws and provisions (see footnote 1) in drafting national implementation measures, although no model law or provision will cover all the individual circumstances and needs of all states. The country can use these models to inform her drafting procedures, tailoring them to fit into the Ugandan context. VERTIC also has the counter-terrorism legislation and resources page where there are links to model measures relating to counter-terrorism in general and to international money laundering in particular. There are also links to model law resources in the Exports Control section.

A harmonised international regime that enhances biosecurity is needed to reduce the risk of bioterrorism (Atlas and Reppy, 2005). Like other security regimes, this will entail mutually reinforcing strands, which need

to include: enactment of legally binding control of access to dangerous pathogens, transparency for sanctioned biodefence programmes, technology transfer and assistance to developing countries to jointly advance biosafety and biosecurity, global awareness of the dual-use dilemma and the potential misuse of science by terrorists, and development of a global ethic of compliance.

In an attempt to assist countries in drafting legislation to implement the 1972 Biological and Toxin Weapons Convention and the biological weapons-related provisions of UN Security Council Resolution 1540, VERTIC has, for example, developed a "*Sample Act*" (see footnote 1). It is a tool which legislative drafters may freely use, while taking into account their country's legal framework, level of biotechnological development, and other national circumstances:

> "*Legislation to prevent and prohibit biological weapons activities should include offences and penalties for any misuse of biological agents and toxins by non-State actors, as well as provisions enabling a State to effectively regulate activities. These two approaches together form a robust deterrent against those who would spread fear and panic, injury and death through the intentional release of disease"* (VERTIC, 2009).

VERTIC has also developed "*Regulatory Guidelines*" for States based on the Sample Act to guide States when

engaged in the process of preparing regulatory and administrative measures to supplement their primary legislation for national implementation of the BWC as well as the biological weapons-related provisions of the UN Security Council Resolution 1540. The guidelines consist of suggestions, tips and links to examples of best practices which States may review and adapt to local circumstances. Part of these Guidelines focuses on biosecurity. They also provide guidance on the establishment of control lists for biological agents, toxins, and dual-use equipment and technology, including intangible technology (see footnote 1).

Biosafety and biosecurity measures implemented by other countries are usually meant to protect personnel from unintentional exposure to and prevent unauthorised access to hazardous biological materials (EU, 2006). These measures usually consist of a combination of laws, regulations and standards for biosafety and biosecurity. A majority of States which have already implemented measures to minimise risks focus their national legislation, regulations and standards on safeguarding the workforce handling biological materials and on the protection of the environment, including the population, against accidental release or loss of hazardous materials.

Based on national statements, the report of the 1540 Committee to the UN Security Council of April 2006 on the status of implementation of national legislative and other measures for the physical protection of BW-related materials counts 48 States having legislation in place that

provides for licensing or registration requirements for hazardous biological materials and indicating that they have specific laws and regulations addressing different safety and security concerns. With regard to enforcement measures, most of these States have indicated that their penal codes or specific laws contain criminal or administrative penalties against violations of safety and security requirements. Compared with the global occurrence of a wide range of micro-organisms of concern and the need for medical, veterinary or phytosanitary diagnosis relating to diseases caused by these agents, the number of States that have implemented respective legislative and other measures seems surprisingly small (EU, 2006).

The July 2008 Report of the Committee established pursuant to resolution 1540 identifies specific measures that States have in place to implement resolution 1540, including steps they have taken since 2006[3]. They range from developing new institutional means to incorporate the obligations of resolution 1540 in national practices to adopting new legislation and enforcement measures, executing new policies and creating new assistance programmes directed towards implementation of the resolution. Overall, according to this report, there has been a qualitative improvement in progress towards achieving full implementation of the resolution.

International agreements like the 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological

[3] See: http://www.un.org/sc/1540/committee reports.shtml

Methods of Warfare; and the Biological and Toxin Weapons Convention (BTWC or BWC) which was signed in 1972; are crucial to creating a normative framework and umbrella under which regional and national non-proliferation efforts can thrive. But these need to be domesticated via national legislation. National legislation can then be used to implement the tenets of international treaties and agreements, and to issue additional national guidance (UNAS, 2008). Article IV of the BTWC, for example, requires that:

> *Each State Party shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.* [4] (EU, 2006).

The precise details of what measures are necessary to accomplish such a complicated task have been left to the discretion of individual States Parties. Different national circumstances and legal systems will necessitate different approaches to implementing the provisions of the Convention. VERTIC, as discussed above, can continue to co-operate with Uganda in the development

[4] See: http://www.opbw.org/; see also: http://www.unog.ch/80256EDD006B8954/(httpAssets)/699B3CA8C061D490C1257188003B9FEE/$file/BWC-Background_Inf.pdf

of legislation to implement the BWC, including biosecurity measures.

Some States, especially those implementing legislation after 9/11, focus their approaches on the physical protection of BW-related biological materials to prevent unauthorised access by theft or diversion by non-State actors, including terrorists (EU, 2006). For example in the United States, the following pieces of legislation have been enacted:

- USA Patriot Act of 2001 criminalises possession of biological weapons;
- Bioterrorism Preparedness Act of 2002 *inter alia* requires registration of facilities that work with select agents (human, plant or animal) and regulates transfers of select agents and requires background checks for personnel;
- Pandemic and All-Hazards Preparedness Act of 2006 *inter alia* establishes a national organisation for health preparedness and response and establishes an R&D organisation to improve and facilitate development of advanced countermeasures (UNAS, 2008).

Additionally, some States have found value in considering integrated legislation that addresses national implementation of both an arms control treaty and of other treaties (see footnote 3).

Recommendation 4

Uganda may wish to consider amending existing legislation or developing a stand alone Act for the comprehensive prevention and prohibition of biological weapons proliferation. This could include provisions referring to the biosafety and biosecurity measures discussed in the conclusions.

As biosecurity is a relatively new and rapidly developing field, many countries have yet to devise or implement laws specific to biosecurity (OECD, 2009 some cases, it may be possible to adapt existing laws within related areas like national security and bioterrorism. Tables 2 and 3 show current legislation in Uganda with a bearing on biosafety and biosecurity. These Acts could potentially be adapted and/or integrated to start addressing this relatively new area of biosecurity (see VERTIC's Sample Act and Regulatory Guidelines referred to above, for example).

It may be far simpler and efficient, however, to draft a stand alone Act, in co-operation with VERTIC, for the implementation of the BWC, including biosecurity measures to ensure the non-proliferation of any materials that could be used to develop biological weapons. Such a law could also cover: definitions, crimes and penalties, jurisdiction, control lists, licensing, transfers control, and reporting, inspections and investigations, and the establishment of a BWC National Authority and biological incident response agency. Both VERTIC's *Sample Act* for implementation of the BWC and their *Regulatory Guidelines* provide in detail the sorts of

biosecurity measures, and other measures, Uganda should consider implementing through law and regulations. Both documents are available on VERTIC's website (see footnote 1)[5].

Table 2. Existing legislation in Uganda with a bearing on biosafety and biosecurity

The Animal Diseases Act, 1918	Requires diseased animals to be separated and reported and also states that the Minister has power to declare infected areas.
The Public Health Act, 1935	Has provisions for the prevention and suppression of infectious diseases.
The Plant Protection Act, 1937	Regulates the importation and exportation of plants, the soil and creates offence of release of pests and diseases
The Penal Code Act, 1950	Prohibits engaging in or carrying out acts of terrorism, aiding, financing, harbouring, belonging or professing to belong to a terrorist organisation. A person is presumed to be involved in acts of terrorism if he imports, sells, distributes, or is in possession, of

[5] Appendix C

	any fire arm, explosives or ammunition. The same applies to a person involved in the spread infectious disease, adulteration of food or drink, sell of noxious food or drink, adulteration drugs or medical preparation, offering or exposing for sale such drugs; and most recently.
The Pharmacy and Drugs Act, 1971	Outlines professional misconduct with respect to medicinal drugs.
The National Environment Act, 1995	Provides for the preparation of guidelines for the coordination of a national response to "environmental disasters".
The Water Act, 1997	Prohibits pollution of water.
The Occupation Safety and Health Act, 2006	States that an employer must take reasonable and practicable measures to protect employees and the general public from dangerous aspects of the undertaking and to protect the environment from pollution.
The Anti-Terrorism Act, 2002	Targets people that engage in or carry out any acts of terrorisms. The Act defines an act of terrorism as the manufacture,

	delivery, placement, discharge or detonation of an explosive or lethal device in a place of public use or a state or government facility with intent to cause death or serious bodily injury or extensive destruction. Alternatively, an act of terrorism is the intentional development or production or use of, or complicity in the development or production or use or unlawful possession of explosives, ammunition, bombs or any materials for making any of the foregoing The Act also defines a lethal device as a weapon or device that is designed, or has the capability, to cause death, serious bodily injury or substantial material damage through the release, dissemination or impact of toxic chemicals, biological agents or toxins or similar substances or radiation or radioactive material.

Table 3. Related legislation in Uganda with a bearing on biosafety and biosecurity

The Adulteration of Produce Act, 1901
The Food and Drugs Act, 1959
Extradition Act, 1964
The Venereal Diseases Act, 1977
The East African Community Customs Management Act, 2004
The Occupational Safety and Health Act, 2006

Challenges to Instituting Biosecurity Measures to Prevent Biological Weapons or the Malicious Release of Infectious Agents to Local Communities

Instituting laboratory biosecurity and bioterrorism measures in Uganda is not without challenges (Balinandi, 2009). Operationally, the concept of biosecurity and bioterrorism has not yet been internalized by development partners. This increases budget proposals and runs the risk of development partners refusing to fund such activities. Additionally, with the proliferation of medical and scientific research laboratories around the country, a registry of who owns and does what becomes very difficult; as does the issue of handling biological agents or toxins that pose a threat to public safety. And the cost of technology (e.g., installation of alarm systems and key cards) as well and maintaining accreditation is prohibitive for most labs in Uganda. The main problem, however, is that there is

little emphasis on training /sensitization of the laboratory community on safety related issues.

Recommendation 5

Agricultural GMO activities require different biosafety measures than scientific and medical laboratory work on human, plant and animal pathogens and toxins. Therefore, Uganda should move to establish a separate national GMO law and regulations to address issues around the research and commercial development of genetically engineered plants and animals.

With the National Biotechnology and Biosafety Policy now in place, Uganda National Council for Science and Technology has drafted a Biotechnology / Biosafety Bill which, among other things, seeks to establish a regulatory structure to oversee the commercialisation of agricultural GMOs so as to minimise and manage any potential risks to the environment or human health that may be associated with them (UNCST, 2009).

While Uganda considers enactment of a biosafety law to establish a regulatory system to assess and manage any potential risks from agricultural GMOs, such regulatory systems have been established in many other countries in Africa and around the world. South Africa passed its Genetically Modified Organism Act in 1997. The South African biosafety regulatory system has been operational for over ten years, approving numerous field trials and commercial releases (Jaffe, 2004). Kenya approved the Biosafety, Act in 2009. This law will replace the use of

existing Kenyan laws to regulate confined field trials and add a regulatory system to address commercial releases. [6] Burkina Faso passed a biosafety law in 2006 and has established a National Biosafety Agency and regulatory system that has approved one commercial product (*Bt* cotton). These pieces of legislation have, in some, established various Authorities that carry the day to day functions under the said legislation. The Act therefore instead of having the existing legislation repealed or amended ,it recognizes the existence of the said legislation and it is for this reason that section 3 of the Biosafety Act that the provisions under the Biosafety Act will be in addition to those under the existing legislation.

Other countries in Africa that have or are in the process of enacting biosafety laws which establish biosafety regulatory systems for GMOs include Mali and Ethiopia. Numerous developed countries also have used either existing law or specific Biosafety laws to establish regulatory systems for agricultural GMOs, such as the EU, the United States, Argentina, and Taiwan (Jaffe, 2004). Therefore, it is common practice around the world to establish a biosafety law and regulatory system to regulate agricultural GMOs. In each instance, those laws address the unique issues around agricultural GMOs and leave the regulation of laboratory biosafety and biosecurity for medical and scientific labs working with pathogens and infectious agents to be addressed with other new or existing laws. Thus, it would be appropriate for Uganda to follow the approach of its

[6] See: (http://www.biosafetykenya.co.ke/bio-act.php

African neighbours and developed countries and pass a biosafety bill that solely addresses agricultural GMOs.

Recommendation 6

Consensus was reached on definitions on biosafety in the GMO context and biosafety and biosecurity in the laboratory context and also in the BWC context. The Committee recommends that these are the definitions pertinent to the Ugandan context:[7]

Defining Biosafety and Biosecurity in a Laboratory Context with Pathogens and/or Infectious Agents

According to the World Health Organisation (WHO), laboratory biosafety and biosecurity are two complimentary but distinct concepts. While they mitigate different risks, they share a common goal: keeping valuable biological material (VBM) safely and securely inside the areas where they are used and stored (WHO, 2006). Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins or their accidental releases (WHO, 2006). Laboratory biosecurity on the other hand describes the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release, retention or transfer of

[7] For a comparison of the similarities and differences between GMO and medical and scientific laboratory activities, see paper by Greg Jaffe in Appendix A of this report.

valuable biological materials and agents (including pathogens and toxins) within labs (WHO, 2006).

Laboratory biosecurity may be addressed through the coordination of administrative, regulatory and physical security procedures and practices implemented in a working environment that utilizes good biosafety practices, and where responsibilities and accountabilities are clearly defined. Because biosafety and laboratory biosecurity are complementary, the implementation of specific biosafety activities already covers some biosecurity aspects and *vice versa*. The systematic use of appropriate biosafety principles and practices reduces the risk of accidental exposure and paves the way for reducing the risks of VBM loss, theft or misuse caused by poor management or poor accountability and protection. Laboratory biosecurity should be built upon a firm foundation of good laboratory biosafety (WHO, 2006).

Definition of Biosafety and Biosecurity from the Biological and Toxin Weapons Convention (BTWC) Perspective

Definition

In the context of the BWC, an understanding was reached at the Meeting of States Parties in 2008 that:

"…*biosafety* refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and *biosecurity* refers to the protection,

control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material…" (Report of The Meeting of States Parties, BWC/MSP/2008/5, 12 December 2008). States further agreed on the need for "…National authorities defining and implementing biosafety and biosecurity concepts in accordance with relevant national laws, regulations and policies, consistent with the provisions of the Convention and taking advantage of relevant guidance and standards, such as those produced by the FAO, OIE and WHO. VERTIC's *Sample Act* for implementation of the BWC and their *Regulatory Guidelines* provide in detail the sorts of biosecurity measures, and other measures, Uganda should consider implementing through law and regulations[8].

Definition of Biosafety as it Relates to Research and Commercialisation of GMOs for Agricultural Purposes

Definition

Biosafety when referring to development and use of GMOs, means principles, technologies, practices, and measures implemented to prevent a GMO from having a potential adverse impact on humans, animals or the environment.

[8] Both documents are available at http://www.vertic.org/NIM/tools/model_laws/#biological.

In agriculture, (including animal husbandry, fishery and forestry), the concept of biosafety involves assessing and monitoring the effects of possible gene flow, competitiveness and the effects on other organisms, as well as possible deleterious effects of the products on health of animals and humans..[9])

The use of the term "biosafety" for GMOs and its meaning derives in part from the Cartagena Protocol (Appendix D[10]), an international sub-agreement to the Convention on Biological Diversity that came in effect on September 11, 2003 (Secretariat of the Convention on Biological Diversity, 2000). Its purpose is to establish a common and coordinated approach among countries to address potential risks of living modified organisms (which are almost identical to GMOs) and provide a degree of certainty in the field of biosafety regulation. It balances the needs of trade among nations, the potential benefits of Living Modified Organisms (LMOs), and protection of the environment (Mackenzie *et al*, 2003; Jaffe, 2005). The Protocol does not have a definition of "biosafety" but it seeks to protect biological diversity from the potential risks posed by LMOs (Secretariat of the Convention on Biological Diversity, 2000).

The scope of the Biosafety Protocol is the transboundary movement, transit, handling and use of LMOs produced through modern biotechnology (which includes genetic engineering). The Protocol attempts to address any potential effects of LMOs on conservation and

[9] See: (http://www.fao.org/docrep/003/X6730E/X6730E08.HTM
[10] Appendix D

sustainable use of biological diversity. Therefore, the Protocol sets forth rules and parameters for managing any risks of LMOs that might impact biodiversity and/or the environment through application of risk assessment and risk management tools (Secretariat of the Convention on Biological Diversity, 2000).

The Biosafety Protocol is not self-implementing so countries need to establish a national biosafety regulatory system (Jaffe, 2005). One definition of such a system is "a regulatory regime responsible for assessing and managing the full range of potential risks that could be posed by GMOs. A biosafety regulatory system addresses potential risks to the environment and biological diversity as well as any food/feed risks or other safety related issues involving GMOs and their products (e.g., worker health, drug safety, etc.)." (Jaffe, 2009). Thus, the regulatory system is supposed to manage risks but allow safe products to be developed and marketed. It can be established by using existing laws, such as plant protection laws, food safety laws, and pesticide laws, or a country can enact a new law, such as a biosafety law that addresses only GMOs.

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APPENDICES

APPENDIX A

Committee Bios

MAXWELL OTIM ONAPA

Dr. Otim Onapa is the Deputy Executive Secretary of the Uganda National Council for Science and Technology (UNCST) where he has been stationed since 2006. His responsibilities include providing leadership and technical support in the design, development and implementation of programmes and projects. Previously, Dr. Otim Onapa worked at the National Agricultural Research Organisation (NARO) as a Research Officer, Infectious Disease, Livestock Health Research Institute (2000 – 2006) and still at the same institute between 1994 and 1999 as a Research Assistant. Previously (1992-1994), he had worked as a Veterinary Research Officer, Microbiology, Animal Health Research Centre, Entebbe. Academically, Maxwell has a PhD from the Royal Veterinary and Agricultural University, Copenhagen; an MSc (Tropical Veterinary Epidemiology) from the Free University of Berlin/Addis Ababa University; and a Bachelor of Veterinary Medicine (BVM) from Makerere University, Uganda. Dr Otim Onapa has published widely and has had additional

professional training in various areas including strategic management, molecular diagnostic PCR training, laboratory diagnosis of avian influenza, among others.

GEORGE WILLIAM LUBEGA

Dr. George William Lubega is a molecular biologist and Professor of Parasitology and Molecular Biology at Makerere University. He has been Head of Department at the University for over 8 years. Dr Lubega is a qualified Veterinarian (Makerere University 1982) and did his Ph.D (1991) in molecular and biochemical parasitology at McGill University in Canada after which he undertook postdoctoral studies in molecular cloning at the same institution. During this period he worked extensively on the biochemical and molecular pharmacology of anthelmintic resistance using cloned genes and recombinant proteins. He returned to Uganda in 1994 and continued to work on anthemintic therapeutics, and drug & vaccine target discovery and validation for trypanosomiasis, onchocerciasis and theileriosis. His work includes recombinant vaccinology against trypanosomes and ticks, molecular diagnostics and study of drug resistance in trypanosomosis; molecular epidemiology of malaria and population genetics of crops such as bananas and beans. His recent major contribution is the demonstration of tubulin as promising vaccine target for human and animal trypanosomiasis. At Makerere, through competitive research grant awards, he helped to found the molecular biology programme and laboratory. The lab is located in the Department of Parasitology in the Faculty of Veterinary Medicine (Makerere University). The

laboratory is now the heart of molecular biotechnology research & training at Makerere and Dr Lubega is the main instructor and coordinator of these activities. It is equipped with all the instrumentation necessary for basic research in molecular biology, cell biology and biochemistry and applied biotechnology including proteomics, electroporation technology and RNAi. He has more than 70 publications in peer reviewed journals or conference proceedings.

BARBARA M. ZAWEDDE- MUGWANYA

Barbara joined the Program for Biosafety Systems (PBS) in September 2003 as a Research Assistant. This close to 6-years work experience exposed her to implementation of various biosafety activities including biosafety policy development process, biosafety capacity building and communication, risk assessment research, and development of regulatory approval strategies including developing national (Uganda) guidelines for contained and confined research on GMOs. She subsequently participated as a *Visiting Scholar* at Michigan State University (USA) in the development of a web-based biosafety resource for African regulators in the area of Crop Biotechnology, under the NEPAD Science and Technology Programme. Recently (February 2009) she was contracted by Uganda national Council for Science and Technology (UNCST) to draft the National Biosafety Strategy, 2009-2014. She has also attended a number of biosafety-related short courses including 'Agricultural Biotechnology', 'Environmental Biosafety' and 'Intellectual Property Rights' - all at Michigan State University. Furthermore, Barbara participated in the

'Environmental Risk Assessment' short course organized by International Centre for Genetic Engineering and Biotechnology (ICGEB) at Ca' Tron Di Roncade, Italy, and 'Plant Genetic Resources Policies' course at Wageningen, The Netherlands. Academically, Barbara holds a Bachelor of Science (BSc.) in Agriculture and a Masters of Science (MSc.) in Crop Science both awarded at Makerere University, Kampala.

GREGORY A. JAFFE

Gregory Jaffe is a graduate of the Harvard Law School, Cambridge, MA, where he obtained a Juris Doctor (cum laude) in 1988. In addition, he obtained a BA (with High Honors) in Biology and Government (Wesleyan University) in 1984. His areas of expertise include applicable laws and regulations relevant to agricultural biotechnology policy (including both food safety and environmental issues), consumer attitudes regarding biotechnology, the Biosafety Protocol and other international agreements relevant to agricultural biotechnology, and laws and regulations of non-US countries (with special emphasis on developing countries). Since 2002, he has been the Director, Biotechnology Project, Centre for Science in the Public Interest in Washington DC. The Centre works to ensure that agricultural biotechnology is adequately regulated to prevent unacceptable human or environmental impacts while promoting and supporting products which are beneficial to society. Greg's responsibilities include commenting on proposed regulations and guidance, working with other stakeholders to reach consensus solutions to agricultural biotechnology policy issues,

advocating positions at conferences and meetings, researching and writing articles on agricultural biotechnology issues, educating the public about agricultural biotechnology, and lobbying Congress and the executive branch to develop adequate laws and regulations. Greg is also an expert legal consultant on biosafety issues for developing countries, including Kenya, Uganda, Ghana, Nigeria, Mali, Malawi, and South Africa. He has published widely and has served on a number of committees including the US Secretary of Agriculture's Committee on Agricultural Biotechnology and 21st Century Agriculture, 2003-2008.

STEPHEN BALINANDI

Stephen Balinandi has been working for the Centers for Disease Control and Prevention in Uganda (popularly known as CDC-Uganda) for over 10 years. Recruited as a laboratory technologist, he has grown through the ranks and is currently a Medical Research (Lab) Specialist and Head of the CDC Special Pathogens Unit at Uganda Virus Research Institute. Prior to his current position, he was the Head of the Molecular Biology unit at CDC-Uganda and was in-charge of all PCR-related diagnostics. He now oversees the technical operations of the SPB unit that include performing diagnostics on human biological specimens suspected of Ebola, Marburg and other related viral infections. Together with colleagues from CDC-Atlanta, USA, he is also running a project on Marburg transmission studies within the bat populations in Uganda. He holds a Bachelors degree in Biomedical Laboratory Technology from Makerere University, a diploma in Biological Science Techniques

from Uganda Polytechnic Kyambogo – now called Kyambogo University. And, he is currently a postgraduate student of Jomo Kenyatta University of Agriculture and Technology in Nairobi, Kenya pursuing a Masters degree in Laboratory Management and Field Epidemiology (or popularly known as the CDC/FELTP-Kenya program).

JOHN RUSOKE TAGASWIRE

John Tagaswire is a practising scientist and has held academic and service appointments since July 1999. He earned his BSc. in Chemistry and Biochemistry from Makerere University and his MSc. in Toxicology from the University of Surrey, Guildford, UK. Mr. Tagaswire also obtained training in Forensic Toxicology from the University of Florida, USA. His areas of expertise include biochemistry, forensic toxicology, risk assessment, scientific information and biological defence. Currently, he is employed by Government of Uganda working on biological defence (detection, protection, decontamination and environmental issues). He is a level 4 BTEC Biological Professional.

ANDREW KIGGUNDU

Andrew Kiggundu is the Head of the National Agricultural Biotechnology Centre which is based at the National Agricultural Laboratories Institute, Kawanda one of the National research centre's of the National Agricultural Research Organisation (NARO). He is overseeing biotechnology research involving plant molecular biology, diagnostics, genetic engineering and gene discovery for crop improvement, in a multi

institutional environment where NARO, the International Institute of Tropical Agriculture (IITA) and the International Centre for Tropical Agriculture (CIAT) researchers are working in collaboration. Dr. Kiggundu is a visiting scientist at the University of Leeds in the UK, and a member of the International Society for Horticultural Science. Dr. Kiggundu completed his MSc. in Plant breeding '*cum laude*' at the University of the Orange Free State, South Africa and PhD. in Plant Biotechnology at the University of Pretoria also in South Africa.

SCOTT SPENCE

Scott Spence is an attorney with experience in private and public international law. He is the Senior Legal Officer at the London-based Verification Research, Training and Information Centre (VERTIC), where he is conducting a global review of national implementing legislation for the Biological and Toxin Weapons Convention and the biological weapons-related provisions of UN Security Council Resolution 1540. He is also organizing and leading legislative drafting assistance activities, including direct work in capitals, in relation to the implementation of these international instruments. Mr Spence previously worked at Interpol and the Organisation for the Prohibition of Chemical Weapons (OPCW). As Interpol's Biocriminalization Project Manager, he collected and analysed the legislation of 35 countries related to the prevention of biological weapons proliferation. At the OPCW, he assisted over thirty States Parties, often in complex face-to-face discussions, with drafting implementing

legislation for the Chemical Weapons Convention. He has drafted and co-drafted model legislation for the implementation of the Chemical and Biological Weapons Conventions. Mr Spence also worked as a lawyer in New York in international finance. He received his legal training at the University of Virginia School of Law and Leiden University, and earned undergraduate and graduate degrees from the University of Virginia and Harvard University. He is a native speaker of English, speaks French and Spanish and has published widely in international security law and in private international law.

APPENDIX B

Open Session Agenda

CONSENSUS STUDY COMMITTEE OF THE UGANDA NATIONAL ACADEMY OF SCIENCES (UNAS)

Advancing the National Dialogue through a Universal Understanding of Biosafety and Biosecurity in Uganda

Open Session Agenda

Hotel Africana, Kampala, Uganda

Meeting Objective

To provide expert testimony to the UNAS consensus study committee that will assist them in reviewing and assessing the current state of knowledge pertaining to the meaning and scope of biosafety and biosecurity with a view to informing policymakers and legislators in Uganda as they attempt to come up with a pertinent national policy and regulatory framework.

WEDNESDAY, JUNE 10, 2009

09:30 - 10:00:	Registration of Participants
10:00 – 10:10:	**Welcome and Opening Remarks** ▪ **EN Sabiiti** - Uganda National Academy of Sciences ▪ **Maxwell Otim Onapa** - Uganda National Council for S&T
10:10 – 10:20:	Self-Introductions

Session I: Background – Defining Biosafety and Biosecurity

Objective: To provide an overview of the issues that will assist the committee in defining the terms "biosafety" and "biosecurity" in the different contexts in which they are used – agriculture, security, hospital diagnostics, etc. - in an effort (1) to reduce definitional confusion; and (2) to begin recognising discrepancies and areas of agreement between and among definitions.

Moderator: Maxwell Otim Onapa

10:20 – 10:40:	**Keynote Presentation:** Biosafety and Biosecurity Definitions, Scope, Regulation and Overlaps **Edward Katongole-Mbidde**, Uganda Virus Research Institute, Entebbe
10:40 – 10:45:	Vote of thanks (Chair).
10:45 – 11:15	Similarities and Differences among GMO Biosafety, Laboratory Biosafety, and Biosecurity. **Gregory Jaffe,** Centre for Science in the Public Interest, Washington DC
11:15 – 11:30:	Discussion
11:30 – 12:00 :	**COFFEE / TEA BREAK**

Session II: Laboratory Biosafety and Risk Assessment

Objective: To apply the information presented in the Background session in order to categorize levels of biosafety and biosecurity risks associated with work conducted in different laboratory settings in Uganda and attempt to inform the committee on the level of risk these activities pose to human, animal, plant and/or environmental health.

Moderator: Patrick Rubaihayo

12:00 – 12:15	Hospital Diagnostic Laboratories **Ali Elbireer, Infectious** Diseases Institute, Makerere Medical School
12:15 – 12:30	Research and Development Laboratories **George W Lubega,** Dept of Parasitology, Faculty of Vet Medicine, Makerere University
12:30 – 12:45	Agricultural Laboratories doing GMO Research **Andrew Kiggundu,** National Biotechnology Laboratories, KARI / NARO
12: 45 – 13:30	Panel Discussion
13:30 - 14:30	**LUNCH**

Session III: Biosecurity and Bioterrorism

Objective: To guide categorization of the activities conducted in Ugandan laboratories by reviewing previously written national and international agreements.

Moderator: Charles Mugoya, ASARECA

14:30 – 15:00:	Overview of International Conventions & Treaties Relating to Biosecurity & Bioterrorism – definitions and obligations **Scott Spence,** VERTIC, London
15:00 – 15:30:	Discussion
15:30 – 16:00:	Overview of the Uganda Laboratory Systems (non-Agric) Biosecurity and Bioterrorism Measures, Issues and Challenges **Stephen Balinandi**, CDC-Uganda, Entebbe
16:00 – 16:30:	Discussion
16:30 – 17:00:	Overview of the Policy and Regulatory Framework for Biosafety & Biosecurity in Uganda **Paul Kahigi Mwebesa,** Uganda Law Reform Commission, Kampala
17:00 – 17:30:	Discussion
17:30 – 20:00:	**COCKTAIL RECEPTION**

APPENDIX C

Overview of the Policy and Regulatory Framework for Biosafety and Biosecurity in Uganda

Paul Kahigi Mwebesa

Uganda Law Reform Commission, Kampala

Policy and Legal Framework

The National Biotechnology and Biosafety Policy 2008 establishes a system where the country can benefit from modern biotechnology while avoiding possible risks. The policy also states that research, development, handling, transboundary movement, transit, use, release and management of GE products should be undertaken in a manner that prevents risks to human health, biological diversity and the environment. The policy was preceded by the Guidelines on Biosafety in Biotechnology that were published in March 2002. The legal framework on the other hand encompasses regulation and monitoring, criminalisation and trans-boundary enforcement aspects.

Regulation, Monitoring, and Management of Biological Agents

There are a number of laws that have a bearing on regulation, monitoring and management of biological agents. These include the Pharmacy and Drugs Act, 1971 (outlines professional misconduct with respect to medicinal drugs); the Water Act, 1997 (prohibits pollution of water); the National Environment Act, 1995 (sets out standards for air, water, and soil quality among others); the Agricultural Seeds and Plant Act, 1994 (establishes a National Seed Certification Service and standards); the Plant Protection Act, 1937 (regulates the importation and exportation of plants, the soil and creates offence of release of pests and diseases); and the Occupation Safety and Health Act (states that an employer must take reasonable and practicable measures to protect employees and the general public from dangerous aspects of the undertaking and to protect the environment from pollution);

Mechanisms for Public Response to Biological Crises

Legislation in this regard includes the Animal Diseases Act, 1918 (requires diseased animals to be separated and reported and also states that the Minister has power to declare infected areas); the Public Health Act, 1935 (has provisions for the prevention and suppression of infectious diseases); and the National Environment Act, 1995 (provides for the preparation of guidelines for the coordination of a national response to “environmental disasters”).

Criminalizing Acts

The Anti-Terrorism Act, 2002 targets people that engage in or carry out any acts of terrorisms. The death penalty is prescribed for those found guilty. The Act defines an act of terrorism as the manufacture, delivery, placement, discharge or detonation of an explosive or lethal devise in a place of public use a state or government facility with intent to cause death or serious bodily injury or extensive destruction. Alternatively, an act of terrorism is the intentional development or production or use of, or complicity in the development or production or use or unlawful possession of explosives, ammunition, bomb or any materials for making of any of the foregoing The Act also defines a lethal device as a weapon or device that is designed, or has the capability, to cause death, serious bodily injury or substantial material damage through the release, dissemination or impact of toxic chemicals, biological agents or toxins or similar substances or radiation or radioactive material

The Penal Code Act prohibits engaging in or carrying out acts of terrorism, aiding, financing, harbouring, belonging or professing to belong to a terrorist organisation. A person is presumed to be involved in acts of terrorism if he imports, sells, distributes, or is in possession, of any fire arm, explosives or ammunition. The same applies to a person involved in the spread infectious disease, adulteration of food or drink, sell of noxious food or drink, adulteration drugs or medical preparation, offering or exposing for sale such drugs. The following acts are also presumed terrorist acts:

- Voluntarily corrupting or fouling water of public use;
- Sending or delivering any explosive substance or other dangerous or noxious thing;
- Dispensing, supplying, selling administering , giving away medicine or poisonous or dangerous manner; and
- Causing or attempting to cause infectious disease.

Other laws targeting criminal acts include:

- Adulteration of Produce Act;
- The Food and Drug Act;
- Plant Protection Act;
- The Public Health Act;
- Venereal Diseases Act

Transboundary Movement and Enforcement

The East African Customs Management Act of 2004 prohibits the importation and transit of prohibited and restricted goods. Other Acts with similar restrictions include:

- Uganda Citizenship and Immigration Act, Cap 66
- Extradition Act, Cap 117

Current Initiatives

The Biosafety Bill / GMO Bill

Advocates responsible research and development in modern biotechnology and attempts to minimise and manage the risks that may be posed by GMOs to the environment and human health. It also targets ensuring an effective level of protection in the development, safe transfer, handling and use of GMOs that may present a risk of harm to human health or the environment and establishes a transparent and knowledge-based process for reviewing and making decisions on the transfer, handling and use of GMOs and related activities.

APPENDIX D

Similarities and Differences among GMO Biosafety, Laboratory Biosafety, and Biosecurity

Gregory Jaffe

Director, Centre for Science in the Public Interest, Washington DC

Introduction

The presentation consisted of four parts: (1) background on genetically modified organisms (GMOs); (2) international and national regulation of GMOs to ensure "biosafety"; (3) background on life sciences "laboratory biosafety and biosecurity"; and (4) a comparison of GMOs and life science laboratory activities, with conclusions on their similarities and differences.

Background on GMOs

Genetically modified organisms are created by inserting DNA from one organism that codes for a beneficial trait into a different organism, such as an agricultural crop or an animal. That process is conducted in a laboratory at

the cellular level and then the cells are reproduced with the new DNA. The primary crops that have been engineered with new DNA and then commercialized around the world are varieties of corn, cotton, soybeans and canola. Those crops have been engineered with two different types of traits – either with a gene that produces a pesticide in the plant or with a gene that allows the plant to be resistant to certain herbicides.

The pathway to developing a GMO for commercial planting by farmers first involves agricultural laboratory work by life science companies and/or public researchers that is conducted in the laboratory and greenhouses. Then, to collect data on the efficacy and safety of the GMO, confined field trial experiments are conducted on small scale outdoor plots of land with physical and biological containment measures that prevent persistence of the GMO in the environment once the experiment is over. Finally, the GMO is approved by the appropriate regulatory agencies and can then be marketed to farmers to be planted, harvested, and eaten.

Currently, GMOs are grown in over twenty countries around the world, with approximately 114 million hectares grown in 2008. The county with the largest acreage of GMO crops is the United States with 57 million hectares. The countries with the largest number of farmers growing GMO crops are India and China, with a combined 11 million farmers.

Determining the benefits and risks of GMOs needs to be done on a case-by-case basis for both the specific crop and its receiving environment. Some of the benefits of

some engineered crops include increases in yield, reduction in pesticide use, increases in farmer household income, and increases in no-till farming. While the current crops have been found safe by the countries where they are planted, those crops were also assessed for different potential risks. Some of the potential risks to humans from engineered crops might be food safety risks such as introduction into the food supply of a potential allergen or a toxin. Some of the potential risks to the environment from engineered crops might include impacts on non-target organisms, gene flow that impacts biodiversity, or the creation of "superweeds," which are resistant to treatment by current herbicides.

International and national regulation of GMOs to ensure "biosafety."

The Cartagena Biosafety Protocol is an international sub-agreement to the Convention on Biological Diversity that can in effect on September 11, 2003. Its purpose is to establish a common and coordinated approach among countries to address potential risks of living modified organisms (which are almost identical to GMOs) and provide a degree of certainty in the field of biosafety regulation. It balances the needs of trade among nations, the potential benefits of LMOs, and protection of the environment. The Protocol does not have a definition of "biosafety" but it seeks to protect biological diversity from the potential risks posed by LMOs.

The scope of the Biosafety Protocol is the transboundary movement, transit, handling and use of LMOs produced through modern biotechnology (which includes genetic

engineering). The Protocol attempts to address any potential effects of LMOs on conservation and sustainable use of biological diversity. Therefore, the Protocol sets forth rules and parameters for managing any risks of LMOs that might impact biodiversity and/or the environment through application of risk assessment and risk management tools.

The Biosafety Protocol is not self-implementing so countries need to establish a national biosafety regulatory system. One definition of such a system is "a regulatory regime responsible for assessing and managing the full range of potential risks that could be posed by GMOs. A biosafety regulatory system addresses potential risks to the environment and biological diversity as well as any food/feed risks or other safety related issues involving GMOs and their products (e.g. worker health, drug safety, etc…)." Thus, the regulatory system is supposed to manage risks but allow safe products to be developed and marketed. It can be established by using existing laws, such as plant protection laws, food safety laws, and pesticide laws, or a country can enact a new law, such as a biosafety law that addresses only GMOs.

Background on life sciences laboratory biosafety and biosecurity

Life science laboratory activities with organisms usually fall into two categories: (1) medical laboratories involved in the diagnosis and treatment of disease; and

(2) scientific research laboratories involved in research on pathogens and disease agents. For that laboratory work, "laboratory biosafety and biosecurity" can be defined as "practices and equipment put in place to protect workers, the environment, and the community from exposure, infection, and subsequent development of disease from activities conducted in the laboratory with infectious organisms." The organisms involved can be disease agents that are known to be hazardous to humans or animals and result in diseases such as HIV AIDS, Cholera, Malaria, or Swine Flu. The risks are also real and involve occupational risks to people working in the laboratory as well as risks to nearby populations from inadvertent releases into the community.

To reduce the risks from life science work with infectious organisms, there are numerous international and national regulations. At the international level, there are health regulations, laboratory biosafety standards, and the WHO Laboratory Biosafety Manual (3rd edition). At the national level, oversight of laboratories is usually done by ministries of Health, Science and Technology, or other relevant government offices.

Comparison of the GMOs and medical and scientific laboratory activities – similarities and differences

When comparing different activities involving living organisms, it is important to look at what is being conducted and the intent of the person doing the activity. It is also important to determine if the are any risks,

whether those risks are “potential” or real, and whether there is overlap in the people conducting the work. If the risks are similar and the regulated community is the same, it would make sense to regulate the activities and persons together. If the activities, risks, and the regulated communities are different, separate regulatory systems would probably be more appropriate.

When comparing biosafety issues surrounding GMOs and medical and scientific life science laboratory work with infectious agents, there are primarily differences that require different regulatory systems. For GMOs, the primary risks are food safety and environmental and those risks are “hypothetical” because they may or may not actually occur (Jaffe, 2004; GAO, 2002). For work with infectious agents, the primary risks are occupational and involve known risks to human health (if a person is infected, they will get sick). In addition, the pathway for exposure is different; for GMOs, the pathway is primarily through exposure in the food supply whereas for scientific laboratory work, the exposure is from contact with the body (through inhalation or contact with the skin).In fact some life science laboratory work with highly infectious agents could be considered ultra hazardous whereas GMO agricultural work is not.

The intent of the activities, how they are carried out, and the persons conducting the work are also different for GMOs and life science work with infectious agents. For agricultural GMOs, the intent is to produce a product that will be released into the environment for farmers to plant and harvest. The experimental work is conducted

in agricultural laboratories, greenhouses, and farms and is carried out by agricultural researchers and private agricultural life science companies. For work with infectious agents, it is done in private medical laboratories, hospitals, veterinary clinics and scientific institutions by scientists and doctors who are trying to understand, diagnose, and treat infections.

With the differences clearly outweighing any similarities between the activities conducted with agricultural GMOs and medical and scientific laboratory work with infectious organisms, “biosafety” needs to have two different meanings and two completely different regulatory systems: one to regulate agricultural GMOs and one to regulate biosafety and biosecurity for laboratory work with infectious organisms.

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