PROMOTING BIOSAFETY AND BIOSECURITY WITHIN THE LIFE SCIENCES:

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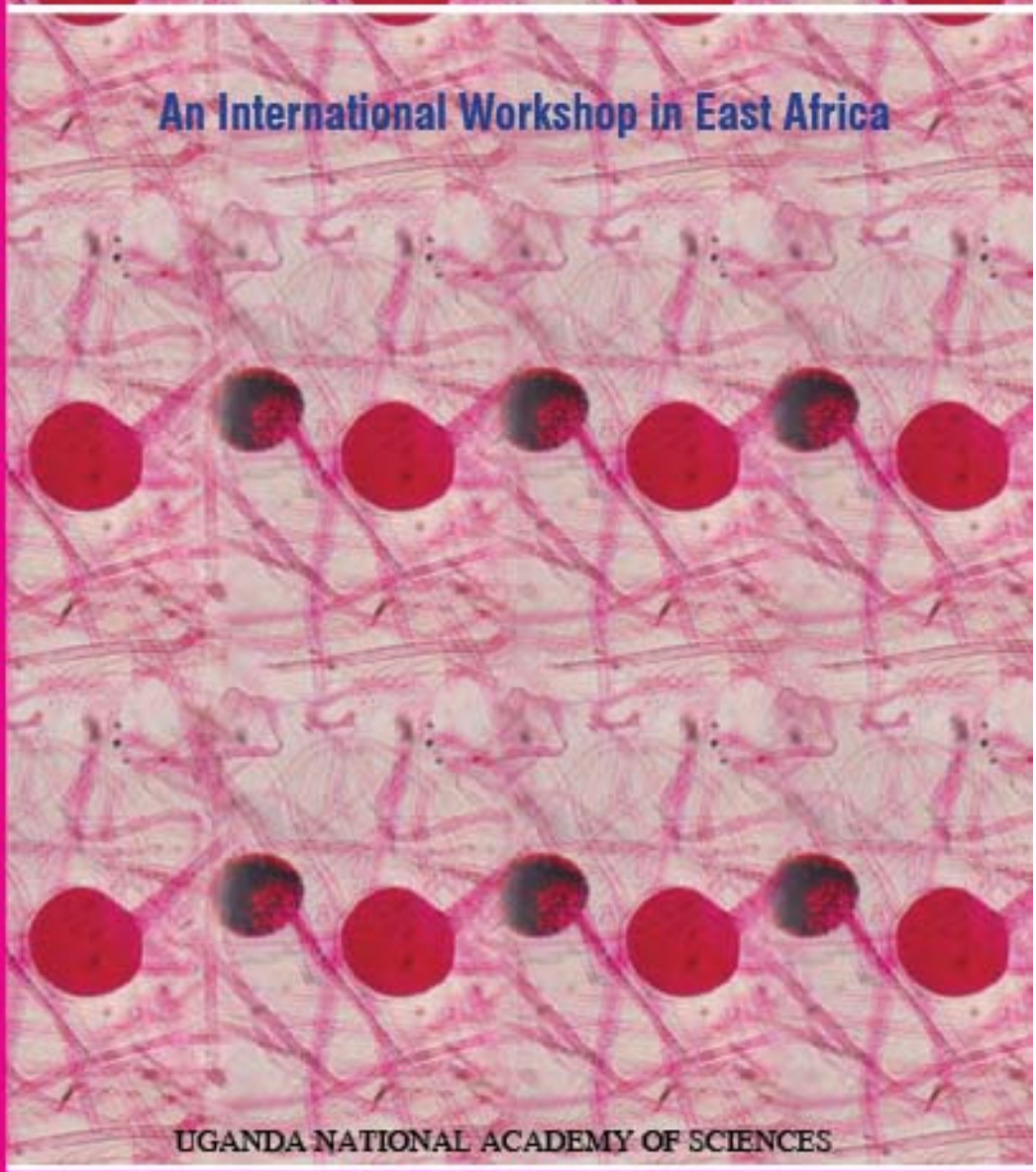
An International Workshop in East Africa



UGANDA NATIONAL ACADEMY OF SCIENCES

UNAS: Science Advisors to the Nation

Promoting Biosafety and Biosecurity Within the Life Sciences: An International Workshop in East Africa

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ISSN: 1819-7086

Support for this project was provided by the Alfred P. Sloan Foundation and US National Academies through the African Science Academies Development Initiative (ASADI).

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, working together in an interdisciplinary and trans-disciplinary manner, whose main goal is to promote excellence in science, and whose vision is to evolve into an eminent body of scientists offering independent evidence-based advice for the prosperity of Uganda.

Reviewers

All presenters at the workshop have reviewed and approved their respective sections of this report for accuracy. In addition, this workshop summary was 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 that will enable UNAS publish a sound workshop summary that meets institutional standards. 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:

Andrew Kigundu, National Agricultural Research Organisation.

Celestino Obua, Associate Professor, Department of Pharmacology and Therapeutics, Makerere University Medical School, Kampala, Uganda.

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The review of this report was overseen by **Professor William B. Banage** (Retired Professor of zoology) and **Professor David A. Relman**,(Stanford School of Medicine) who were 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 the editors and individual authors.

Preface

At the 2007 African Union Summit, science and technology were seen as key drivers of future development in Africa. As a result, a high-level biotechnology panel was established at the summit to consider a strategy for the advancement of biotechnology. This suggests that many policy-makers accept that the life sciences can provide solutions for fundamental challenges to development such as food security, vaccine production and even environmental conservation. While such investment is generally welcomed, international experience has shown that research in biotechnology is not without concern. 'Biosafety' has emerged in some quarters of Africa as an important topic, though often in relation to the specific issues of trialling and trading agricultural crops. However, laboratory biosafety pertaining to scientific experimentation has received less attention.

Biosecurity on the other hand is even less well developed within Africa as a whole compared to any aspects of biosafety. Although some African states, most notably South Africa, have played an active role in discussions at the Biological and Toxins Weapons Convention (BWC), it is clear that a stronger and more coherent position on institutional oversight and regulation issues would be welcomed. This would not only address the need for an 'African voice' on biosecurity issues, but

would also strengthen the negotiating position of those states whose interest is to ensure that development and the sharing of knowledge and technology are placed firmly on the agenda.

The development of laboratory biosafety and biosecurity oversight mechanisms that neither compromise research nor pose an unbearable financial burden on those responsible for their implementation is a significant challenge. Such oversight mechanisms would reduce the risk of harm stemming from inadvertent, accidental and malicious intention. They would also mitigate the potential damage to African scientific development that would result in knowledge, technology, or products, contributing to destructive ends.

Considering that a number of projects relating to biosafety and biosecurity are underway in Africa, there is need for them to be brought together and taken further by devising concrete policy responses and practical institutional measures. Such a step would require a process involving more intensive interactions with a wider audience than have been engaged to date. It is crucial that this includes practicing scientists that will ultimately be responsible for implementing and disseminating oversight procedures.

AIMS OF THE WORKSHOP

The overall aim of the workshop was to promote policies and practices that will reduce the likelihood of the inadvertent or deliberate spread of disease stemming from life science research.

More specific objectives of the workshop were to:

- Bring together leading scientists and policy experts in Africa and beyond to discuss biosafety and biosecurity;
- Build capacity within research institutions in East Africa to devise and undertake laboratory biosafety and biosecurity oversight review procedures;

- Foster links among scientists, national and international scientific organizations and civil society in their own countries and beyond;
- Build capacity within UNAS and collaborating institutions and organizations to initiate further work in organizing and undertaking science policy initiatives;
- Disseminate emerging educational materials and tools; and
- Raise the profile of Africa and African countries in international biosecurity deliberations.

OUTCOMES FROM THE WORKSHOP

Anticipated outcomes resulting from stakeholder dialogue and other discussions brought about by expert presentations at this biosafety/ biosecurity workshop included:

- Commitment from key scientists and policy-makers in Africa to continue and further their engagement with laboratory biosafety and biosecurity;
- Ongoing exchange of knowledge and experience on good practices regarding institutional biosafety oversight and development of new models for oversight in relation to biosecurity that are appropriate for countries in Africa;
- Greater participation of African countries in international policy deliberations and a greater role for African scientists as advisors to their governments for those processes; and
- Forging links between civil society, NGOs, scientific organisations and policy-makers in Africa to take the issues further in the future.

Acknowledgements

We, at Uganda National Academy of Sciences (UNAS) wish to express our warmest appreciation to the individuals and organisations that gave valuable time to provide information and experiences to the meeting through their participation in the workshop. A full list of presenters can be found in Appendices B and D.

The Academy thanks the following individuals for their expert advice, opinion, and willingness to contribute: Ms. Patricia Cuff, Ms. Katherine McClure and Dr. Jo Husbands (all from the US National Academies), Dr. Brian Rappert (University of Exeter), Professor Malcolm Dando (University of Bradford), and Dr. Chandre Gould (ISS). The Academy also wishes to acknowledge the UNAS staff involved in organising the workshop and the production of this workshop report especially Solome Mukwaya and Franklin Muyonjo. We gratefully acknowledge the sponsors (the US National Academies and the Alfred Sloan Foundation) who provided financial support for this activity. Special thanks go to the reviewers who volunteered their time to provide candid and critical comments to ensure that the report is accurate, effective and credible. The views presented in this workshop summary are those of the editors and individual authors, and not necessarily those of Uganda National Academy of Sciences.

Prof. P.E. Mugambi
President
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Contents

Summary and Assessment

In an effort to summarize the critical discussion points covered in the two days of deliberations at the workshop on biosafety and biosecurity within the life sciences, conference moderators met for a break-out session towards the close of the meeting to draft key messages based on the central themes of all the sessions as well as specific presentations and subsequent dialogue. These messages were then presented to the meeting participants for their assessment and their approval. Box 1.1 represents the outcome of this exercise and thus the key messages from the workshop as agreed upon by all the workshop participants. These messages are supported by the papers included in this report.

Box 1.1

Key Messages

A Common Understanding

- A common understanding was sought to clarify the scope of biosafety and biosecurity.

The Scope of Biosafety and Biosecurity

- Biosafety is accepted as essential to keep up with the rapid developments in biotechnology.
- In Africa, primary, biosecurity risk comes from nature and not the laboratory. However, there is a potential for some infectious agents to spread accidentally or deliberately from the laboratory and endanger the public. So, attention to laboratory biosafety and biosecurity is critical.

Legal Frameworks

- Do countries need to start thinking of different policy and legal frameworks for biosafety and biosecurity?
- Individual countries need to adapt their existing or new policy and legal

frameworks to capture biosafety and biosecurity.
- There is need for compliance with and enforcement of existing laws and regulations, including those on bio-piracy and intellectual property rights.

Capacity Building
- There is a need to educate and sensitise people at all levels – policymakers, regulators, scientists/laboratory workers, and the public – on biosafety and biosecurity.
- The responsibility for biosafety and biosecurity lies at multiple levels—individual responsibility, institutional responsibility, and oversight at the national level.
- Capacity building is critical at all levels including: human capacity and infra structure.
- Training and educational materials should be shared and biosafety included into educational curriculums.
- Biosafety and biosecurity are cross-border issues—collaboration should be encouraged.

Role of African Science Academies
- Awareness needs to be raised with policy-makers and scientists.
- The academies should play an active role in advising governments.
- Academies should disseminate key messages from this meeting at subsequent events

Biosafety and Biosecurity: A Common Understanding

There is presently no single definition of biosafey and biosecurity accepted around the world. Taken together, biosafety and biosecurity encompass all of the activities aimed at preventing microbial infections, including those aimed at preventing laboratory workers from becoming infected and those aimed at preventing the release of pathogens from microbiological laboratories. Taken separately, biosafety can be defined as, the development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent unintended transmission of biological agents to workers, other persons, plants, animals and the environment. Biosecurity can be defined as the protection of high-consequence microbial agents and toxins, or critical and relevant information, against theft or diversion by those who intend to pursue intentional misuse (Richmond et.al, 2002). Depending upon

the definition one chooses, biosecurity may be seen as an extension of biosafety aimed at keeping pathogenic organisms in the laboratory and out of the hands of terrorists—a view generally held in the United States and supported by the World Health Organization—or biosecurity may be seen solely as preventing exposure to harmful organisms—a view held by countries such as New Zealand and Australia. Further complicating the situation, the Food and Agriculture Organisation (FAO) of the United Nations defines biosecurity as the management of all biological and environmental risks associated with food and agriculture. In this context, biosecurity consists of ensuring food safety, monitoring the introduction and release of genetically modified organisms and their products, and monitoring the introduction and spread of invasive alien species, alien genotypes, plant pests, animal pests, diseases, and zoonoses. (FAO, 2001). The development or refinement of such biotechnology techniques essentially raises concerns regarding what novel threats might stem from life sciences research, how scientists can contribute to national defence and whether some lines of investigation are too contentious to pursue.

In the conference it was noted that the threat posed by biological agents (infectious disease) to a population can originate in nature or through human actions. Known as "biorisk," it includes biosafety and biosecurity measures aimed at controlling and preventing personal exposure to any biological risks regardless of the source of harm. Through discussions at the meeting it was concluded that the primary biorisk for Africa lies in nature and all the endemic diseases occurring in Africa.

The lack of a clear definition of biosafety and biosecurity and tests that are involved, is a major impediment to developing universal biosafety/ biosecurity guidelines. In recognition of this, at the Sixth Review Conference of the Biological Toxins and Weapons Convention (BTWC), it was agreed that the 2008 states (party to the convention meeting) would discuss and promote a common understanding and effective action on oversight, education, awareness-raising, and the adoption of development of codes of conduct with the aim of preventing the misuse of biotechnology and bioscience (UN, 2006). The decision to focus on

a common understanding of biosafety and biosecurity, as well as developing guidelines, was based on the need for a universal and clear understanding of policies, implementation, and regulations related to biosafety and biosecurity.

Policies and Legal Frameworks

Discussions at this workshop were evidence of the different interepretations of biosafety and biosecurity and thus the different policies and regulations highlighted by the speakers. African speakers tended to focus on national and international agreements that have a direct bearing on developing national biosafety systems such as the UN Convention on Biodiversity (1992), the Cartagena Protocol on Biosafety (2000), CODEX Alimentarius, and the African Model Law on Safety in Biotechnology. In fact, it was noted that national laws must be consistent with pertinent policies on food and agriculture, as well as national development objectives. In this context, a biosafety regulatory system was described as comprehensive in scope when it covers the different stages of development of the genetically modified organism (GMO) such as releases into the environment, confined field trials, releases of commercial products, and consumption as food. It would also analyze the range of potential safety issues associated with GMOs, including the environmental and biodiversity issues highlighted in the Biosafety Protocol, and food safety issues and any other potential safety questions such as worker safety.

Conversely, non-African speakers at the workshop put little emphasis on genetic modification of organisms and their effect on the food supply and environment and greater focus on the the threat of deliberately caused disease from hostile use of biological agents in biowarfare and bioterrorism and the possible future misuse of the results of benignly-intended research in the biotechnology revolution. One speaker focused on what began by identifying points of potential policy intervention and effective policies that formed web of deterrence against State-offensive biological weapons programmes and has now evolved into the idea of a web of prevention against all aspects of misuse. Similarly, the speaker

from the World Health Organization described the spectrum of risks to global health security in today's world and the international legally binding instrument, the International Health Regulations (IHR) (WHO, 2005), that provides for the management of such risks.
A broader perspective was offered from an American speaker stating that biosecurity encompasses all policies and measures taken to secure humans, animals and plants against biological threats regardless of whether they are naturally-occurring or man-made. This includes the prevention, detection and mitigation of damage by disease, pests and bioterrorism to economies, the environment (including water, agriculture and biodiversity) and human and animal health. She goes on to say that systems for biosecurity can be developed at the national level, but have widespread ramifications. Regional and global trade and transportation, for preventing the spread of transboundary diseases, and environmental protection against invasive species are just a few examples of international biosecurity concerns.

One agreemment among the meeting participants was that scientists in all nations need to work with policy-makers in their efforts to make progress toward measures that will ensure biosafety and biosecurity and minimize biorisk. And to develop biosafety and biosecurity guidelines and regulations, high-level interactions are necessary among policy-makers, professional bodies and technical experts involved in biotechnology and other forms of life science research and devleopment. It was also agreed that given the lack of understanding by people of all levels of engagement (e.g., policy-makers, regulators, implementers, scientists and technical workers) emphasis is needed to sensitize and educate those who deal with biosafety and biosecurity in order to close the knowledge gap.

Capacity Building

Building human capacity through education is an important component to better ensuring policies on biosafety and biosecurity are effectively written, implemented and followed. Currently, there is a need to educate scientists, policy-makers and communicators on issues of biosafety and

biosecurity; and a need for more educated dialogue on how best to enforce the regulations and guidelines in critical areas such as laboratory structure and maintenance. The meeting discussants noted that in Africa the infrastructure in many countries is rudimentary and, in some cases, inadequate to actually meet the physical containment requirements necessary to ensure a safe working environment. By sharing training and educational materials, it may be possible to speed the delivery of information that might improve working conditions in some places depending on the target of the materials and the receptivity of the audience. At the national and international levels there are initiatives, guidelines and other resources that could also be shared in an effort to facilitate capacity building in areas of biosafety and biosecurity.

Article IV of the Biological Toxins and Weapons Convention calls for states to hold citizens responsible for violating the convention; thus providing support for the concept of individual responsibility through training, awareness campaigns and communication. The hope is that by educating scientists and others involved in laboratory work there would be greater compliance to rules and regulations once they are made aware of their legal and ethical responsibilities. The 2005 InterAcademy Panel statement on biosecutity maintains that scientists should be aware of, disseminate information about, and teach national and international laws and regulations as well as policies and principles aimed at preventing the misuse of biological research (IAP, 2005). Education is a vital first step towards achieving enhanced systems of research governance that address knowledge and techniques related to dual use[1] although a culture of responsibility is just as vital to instill values as are supervision and oversight (which was identified as critical by the the National Science Advisory Board for Biosecurity working group).

[1] Dual use in this case implies the use of toxins and pathogens for constructive and destructive purposes.

Conclusion: The Role of African Science Academies

National science academies are in an excellent position to become the champions of biosafety and biosecurity by educating and raising awareness among policy-makers and scientists of the importance of biosafety and biosecurity. Through convening and consensus activites, academies can also play a key role in advising governments on issues of biosafety and biosecurity and how the two impact on day-to-day implementation of science and technology. Academies can help to sensitize the government and provide information in order to facilitate a clearer understanding of the issues related to biosafety and biosecurity. At the meeting, participants urged members of science academies to communicate key messages from this workahop at subsequent events such as the Biological Weapons Convention on Oversight Education and the Awareness Creation on Biosafety and Biosecurity that might push the discussions at this conference even further and might promote greater awareness of biosafety and biosecurity issues in Africa.

REFERENCES

FAO. 2001. Committee on Agriculture, Sixteenth Session, online available at: http://www.fao.org/DOCREP/MEETING/003/X9181E.HTM.

InterAcademy Panel. 2005. IAP Statement on Biosecurity. 7 November Trieste: Available at: http://www.interacademies.net/Object.File/Master/5/399/Biosecurity%20St.pdf.

NSABB. 2007. Report of the NSABB Working Group on Oversight Framework Development. Bethesda, MD: NSABB.

Reynolds, M. Salerno and Jennifer G. Koelm. 2002. Biological Laboratory and Transportation Security and The Biological Weapons Convention prepared for National Nuclear Security Administration Office of Non-proliferation Policy (NA-241) U.S. Department of Energy, available online at: http://www.cmc.sandia.gov/cmc-papers/sand2002-1067p.pdf.

United Nations. 2006. Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. BWC/CONF.VI/6 UN: Geneva

1
Overview and Introduction

OVERVIEW

Traditional laboratory biosafety guidelines have emphasised the use of optimal work practices, appropriate containment of equipment, well-designed facilities, and administrative controls to minimize risks of unintentional infection or injury for laboratory workers and to prevent contamination of the outside environment. Although incidents involvingbiosecurity have not been common in Africa, it is important for African countries to either enhance their existing regulations or to create new ones governing laboratory security to prevent such occurrences. This can be done through proper disposal of waste, risk assessment to understand all forms of danger, and developing appropriate safety regulations. Risk assessment involvesconsidering aspects of environmental protection, protection and regulation of the biotechnology developer who operates in a hazardous environment, and protection of the customer. Biotechnology has developed all over the world and has made it possible to produce new products of great medical, agricultural and industrial importance such as highly resistant genetically modified plants and vaccines, which were hitherto unknown, through the use of genetic engineering and radioactive techniques. Biosafety guidelines are therefore important. Developing biosafety and biosecurity guidelines and regulations requires high-level interaction between policy-makers, professional bodies and technical staff, together with all other relevant stakeholders. Development of biosafety/biosecurity is hindered by lack of information on regulations of applications of biotechnology, lack of

an understanding of risks and benefits associated with biotechnology development, and application and a clear definition of biosafety and biosecurity. Bioterrorism came to the limelight after the terrorist attacks of September 11 and the anthrax letter incident(s) in 2001. In Africa, most biotechnology research is aimed at increasing food production. Biorisk includes unintentional exposure, and illegal obtaining of pathogens. Proper biosafety measures are needed in laboratories and in other spheres of public health, and animal health.Training and safety measures are paramount (which include good laboratory practices and waste management). The central issue is that the web of prevention against all aspects of misuse lies in the identification of points of potential policy intervention and effective policies. The Biological Toxins Weapons Convention (BTWC) focuses on in-depth implementation involving codes of conduct and appropriate education for life scientists. An integrated overview of all the policy intervention points and potential policy options in a web of prevention are needed to support new educational modules for life scientists. This session led to heated discussions where participants asked about mechanisms that theWHO has put in place to ensure that funding focuses on tropical diseases that have not been addressed before. It was also pointed out that research information exists in Africa but the implementation aspect has been a major problem due to gaps in capacity building. The discussion raised questions regarding the point at which biosafety becomes biosecurity. It was understood that the web of security should trickle down from the highest levels to the lowest levels that involve practitioners. With regard to regulation, there was a strong view of the need for regulations that control the movement of samples from one country to another especially if the source country has the equipment and expertise to carry out the required studies and tests.

PROMOTING BIOSAFETY AND BIOSECURITY WITHIN THE LIFE SCIENCES

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The programme for the meeting addresses the most important elements of biosafety and biosecurity. It is however important to pay attention to how developing countries can address these issues and how the outcomes of the workshop would be implemented by resource-limited countries like Uganda. Below are some definitions of key words (Richmond et.al, 2002).

- **Biosafety**: Development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent unintended transmission of biological agents to workers, other persons, plants, animals and the environment.
- **Biosecurity**: Protection of high-consequence microbial agents and toxins, or critical and relevant information, against theft or diversion by those who intend to pursue intentional misuse.
- **Biologic Terrorism**: Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals or plants) for terrorist purposes**.**
- **Risk**: A measure of the potential loss of a specific biologic agent of concern, on the basis of the probability of occurrence of an adversary event, effectiveness of protection, and consequence of loss.
- **Threat**: The capability of an adversary, coupled with intentions, to undertake malevolent actions.
- **Threat assessment**: A judgement, based on available information, of the actual or potential threat of malevolent action.
- **Vulnerability**: An exploitable capability, security weakness or deficiency at a facility. Exploitable capabilities or weaknesses are those inherent in the design of layout of the biologic laboratory and its protection, or those existing because of failure to meet or maintain prescribed security standards when evaluated against defined threats.

- **Vulnerability assessment**: A systematic evaluation process in which qualitative and quantitative techniques are applied to arrive at an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interests.

The terrorist attacks of the past few years have created more awareness that the threats from biological weapons need to be tackled urgently and on many fronts especially biosafety and biosecurity by all nations. The best scientists in all nations must support policy-makers in their efforts to make progress toward measures that will ensure biosafety and biosecurity to counteract the threat from advances in life-sciences technology that could be misused by governments or as terrorist threat agents. It is also important to devote attention to blocking the proliferation of biological weapons capabilities around the world.

Most scientists are aware of the constant threat of spread of diseases from laboratories. This might happen if any of the following is not properly catered for namely: 1) physical security; 2) employee security; 3) access controls to laboratories and animal areas; 4) procedures for agent inventory and accountability; 5) shipping/transfer and receiving of select agents; 6) unintentional incident and injury policies; 7) emergency response plans; 8) policies that address breaches in security; and 9) security of data and electronic technology systems.
Traditional guidelines for laboratory biosafety have emphasized use of optimal work practices, appropriate containment equipment, well-designed facilities, and administrative controls to minimize risks of unintentional infection or injury for laboratory workers and to prevent contamination of the outside environment. Although clinical and research microbiology laboratories might contain dangerous biologic, chemical and radioactive materials, to date only a limited number of reports have been published of materials being used intentionally to injure laboratory workers or others. Recently, concern has increased regarding the possible use of biologic, chemical, and radioactive materials as agents

of terrorism. The use of Polonium 210[2] recently is still a vivid memory. Such incidents are yet to be reported in developing countries but existing regulations need to be enhanced and new regulations governing laboratory security need to be developed to prevent such incidents.

The safety of the environment where the clinical or research laboratory is situated needs to be protected. It is not uncommon, in developing countries, to see medical waste disposed off in a very unsatisfactory manner. Where attempts at incineration are made, one sees smoke in the sky because the technology used is inadequate. In some cases the waste and ashes are disposed off in a manner that allows the chemicals to seep into the ground and contaminate water. This is hazardous to the users and underscores the need to protect sources of drinking water.

In the modern era of biotechnology, two environments are in danger of exposure to hazardous biotechnology products, namely, the developmental laboratory and the field where the technology is applied. Both scenarios require separate risk assessments to understand the physical, chemical and biological dangers involved and to develop appropriate safety regulations for each environment.

The development or refinement of biotechnology techniques is essentially a laboratory-based activity. The end products of this activity, either as novel assay systems, genetically modified organisms, or even recombinant vaccines, are intended to find their way outside the development laboratory either into the field, or into other less specialised diagnostic, laboratory situations. This raises concerns regarding what novel threats might stem from life sciences research, how scientists can contribute to national defence and whether some lines of investigation are too contentious to pursue. Thus, the need for biosafety

[2]In 2006, Polonium 210 was used to kill Alexander Litvinenko a former Russian spy who escaped prosecution and received political asylum in Great Britain. On November 1, 2006 he fell sick and died two weeks later. The postmortem showed he had died of polonium-induced acute respiratory syndrome. The material (polonium 210) was traced to 40 separate premises, 1500 people were at risk and 17 were actually contaminated. The chemical was put in a cup of coffee from which Latvinenko took one sip. The person who took tea in the same cup after it had been washed was also highly contaminated with the chemical but survived death. (www.news.bbc.co.uk " Litvinenko poisoning")

and biosecurity measures to mitigate and regulate potential threats is apparent. The development and refinement of biotechnology techniques require safety frameworks which have different terms of reference from those needing to be applied during the field use of the outputs of the developmental biotechnology laboratory.

We have then two different scenarios for risk assessment: the first scenario aims principally at the protection of the environment and the protection and regulation of the developer who operates in a considerably more hazardous environment than his/her customer; and the second scenario aims at the protection of the customer and the environment when handling the output of the developer.

Safety concerns in laboratories developing biotechnology systems are complex. Side by side can be found chemical, physical and biological hazards, and the investigators for his/her own safety must become familiar with all of them. Chemical hazards are common to all laboratories and are generally well recognised. All chemicals in use are subject to stringent international labelling requirements, which announce the degree of caution to be used by the operator and graphically point out the mechanisms by which damage may be caused. Disposal and spill information is also contained in abbreviated form to ensure that the chemical is properly used, disposed of or cleaned in the event of an accidental spillage.

Developed countries have initiated systems for control of substances hazardous to health; these systems have different names depending on the country, but aim to achieve the same ends. These systems are very labour-intensive and time-consuming but should have the merit of ensuring that the legal and moral obligations of all parties involved in the manufacture, use, disposal and transport of substances hazardous to health are enforced.

Physical hazards also exist and present significant hazards in the laboratory, including: the risk of electric shock from high powered electrophoresis equipment; the danger of exposure to high intensity

ultra violet radiation; and, precautions to be taken when handling liquefied gases.

Radioactive compounds have been used for many years as tracers and probes in biological systems and the control of their use and disposal is of great importance and has received much attention. Wherever possible, alternatives to radioactive detection methods should be used, but certain applications are still easier and even better than using radioactive substances.

Biotechnology offers tremendous opportunities and inexpensive solutions to some of the pressing problems in health, agriculture, industry and the environment. Great advances have been made in the development of new products through biotechnology in the developed world, while efforts to harness such technologies are just beginning to emerge in the developing countries.

Developments in science, especially both traditional and modern biotechnology, have made it possible to produce new products which were hitherto unknown. Genetic engineering and recombinant DNA (rDNA) technology hold enormous potential in delivering economically important life-saving products and technologies. At the same time, this area has the inherent probability of delivering unintended effects through wrong expressions which could pose environmental risks and hazards to human and animals. This has been quite obvious in cases where rDNA has been used in molecular genetics to produce transgenics. This technology has been in existence since the early 1970s when scientists discovered that rDNA could be used to "create" new organisms. This being one of the new frontiers of science, it has become a challenge to the theory of evolution and as a result it has created fear among the public and raised matters of ethical concerns. The debate regarding the possibilities of producing dangerous organisms through the use of biotechnology and releasing them to the environment still continues, even though rDNA technology has now been in existence

for several years. Early scientists responded to the criticisms from the public by calling the Asilomar Conference in 1974.[3] At the same time, there was a general moratorium on experiments using rDNA. Later, precautionary measures were suggested and these culminated in the production of biosafety guidelines at a national level. Such guidelines were expected to cover not only laboratory experiments but also field releases on both small and large scale.

Biotechnology is but an enabling technology with broad applications to many different areas of humankind's interactions with the environment. For agriculture, biotechnology has the potential to increase production and productivity, enhance the environment, and improve food safety and quality. The challenge, however, is whether it is possible to strike the proper balance between direction and oversight to allow biotechnology to be safely applied and to flourish. To meet this challenge there is a need to effect perception changes and paradigm shifts.

This requires harmonisation of regulations as a key component in allowing biotechnology to deliver its promise to Africa, as well as the world. This does not mean that all should have the same regulations, but that we should develop equal or equivalent standards; harmonisation requires collaboration between individuals, institutions and sovereign states. Indeed, collaboration and cooperation, whether in the development of biosafety regulations for environmental safety or in technology transfer for food production, are more important in our increasingly international society.

The transfer of biotechnology and its products to developing countries presents a complex challenge, of which the biosafety and biosecurity issues are an integral part. Biosafety and regulation of biotechnology

[3] The Asilomar Conference in 1974 was organized to review scientific progress in research on recombinant DNA molecules and to discuss appropriate ways to deal with the potential biohazards of this work. Of particular concern was the issue of whether the pause in certain aspects of research in this area called for by the committee on Recombinant DNA molecules of the National Academy of Science USA should end and if so how the scientific work could be undertaken with minimal risks to workers in labs, to the public at large and to the animal and plant species sharing the eco system. (USNAS, 1975).

activities have been at the forefront of the biotechnology debate for almost a decade now, especially in developing countries. However, such biosafety and biosecurity debates and forums for discussions and interactions, which are commonplace in developed countries and provide learning opportunities, are limited in developing countries, which at the same time, need such experiences in order to develop their own biosafety and biosecurity guidelines. Developing biosafety and biosecurity guidelines and regulations needs high-level interaction between policy-makers, professional bodies and technical staff involved in biotechnology development. Considering the limited resources and information available in developing countries, it is reasonable to assume that success will only come through externally supported meetings and workshops, which will provide a forum for exchange, open discussions and interactions with people from different backgrounds on the impact of biotechnology in agriculture, health, social structure and environment.

There are four major areas responsible for hindering the development of biosafety/biosecurity guidelines. These are: 1) lack of information on existing national and international efforts at regulation of biotechnology applications; 2) a clear understanding between potential risks and benefits of modern biotechnology, including the issue of biodiversity and the environment; 3) the state of the art in the development of the technology on the one hand and its application on the other; and 4) the actual definitions of biosafety and biosecurity and tests that are involved.

Policy makers in countries where biotechnology research is conducted and transgenic organisms are developed, tested, imported, exported or used should develop a biosafety and biosecurity regulatory structure. Some countries in Africa, notably Egypt, Kenya, Uganda, South Africa and Zimbabwe are developing oversight mechanisms for biotechnology and other related advances in sciences and technology.

The dialogue can help ensure that laboratory biosecurity is a priority for both new and existing laboratories. The following biosecurity policies and procedures will be taken into consideration: risk and threat assessment, facility security plans, physical security, data and electronic

technology systems, security policies for personnel, policies regarding accessing the laboratory and animal areas, specimen accountability, receipt of reagents into the laboratory, transfer or shipping of select agents from laboratories, emergency response plans, and reporting of incidents, unintentional injuries, and securities breaches. In many developing countries these aspects are not addressed or implemented to the extent required because of financial constraints, personnel not committed, laboratories ran by development partners giving rise to the feeling among locals of not being concerned, fear of being deemed incompetent if injuries are reported, and fear of taking prophylactic drugs in the case of suspected HIV infection. No doubt, policy-makers will take note of the fact that translation of policies into action will cost money; hence the need to commit resources to maintain the required level of security. This is more so in areas where outbreaks of highly pathogenic organisms, such as, viral haemorrhagic fevers, plague, etc are rampant needing biosafety level 3 and 4 laboratories to address such threats.

Finally, the proceedings will be read with a lot of interest from the scientific fraternity, eagerness from policy-makers and a lot of expectations from the communities. Coordination and collaboration through networking will strengthen the weak and provide the opportunity for the strong to assist and improve biosafety and biosecurity of laboratories in resource limited countries.

REFERENCES

BBC.2006.Latvinenko Poisoning. Available online at www.news.bbc.co.uk

National Academy of Sciences. 1975. Proceedings of the National Academy of Sciences USA, Vol.72, No. 6, pp. 1981-84.

Jonathan Y. Richmond and Shanna L. Nesby-O'Dell.2002. Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents. Online available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5119a1.htm

GLOBAL HEALTH SECURITY IN THE 21ST CENTURY

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"As the determinants and consequences of health emergencies have become broader, so has the range of players with a stake in the security agenda."
Dr Margaret Chan, Director-General, World Health Organization introducing the World Health Report 2007(WHO, 2007a)

Introduction

This paper outlines the spectrum of risks to global health security in today's world and the international legally binding instrument, the International Health Regulations (IHR) (WHO, 2005), that provides for the management of such risks. It describes the activities of the operational arm of the World Health Organization's outbreak alert and response operations, including the Global Outbreak Alert and Response Network (GOARN, 2008). Selected activities such as laboratory biosafety, laboratory biosecurity and biosecurity of research into life sciences are also described. The paper emphasizes the need for intersectoral collaboration for the effective management of risks to global health and security.

The spectrum of risks to global health security

The World Health Report 2007 identifies a number of risks to global health security as follows: (i) epidemic-prone diseases often originating from domestic and wild animals, such as Marburg haemorrhagic fever, Severe Acute Respiratory Syndrome (SARS), avian influenza and foodborne diseases; (ii) international crises and humanitarian emergencies that severely afflict individuals and health systems; (iii) deliberate use of chemical, radioactive and biological agents that affect health; and (iv) environmental disasters such as those caused by environmental and climate changes.

The deliberate use of biological, chemical or radiological agents poses a distinct challenge to health security. The WHO's global scientific networks are well placed to respond to the health effects of these hazards by using the existing frameworks utilized for other health emergencies. However, the national and international security aspects of such events fall beyond the WHO's public health mandate. For ministries of health, the dilemma is one of priority and resource allocation for the management of these low-probability but high consequence events compared with other health emergencies and the regular health needs of the population. The WHO advocates the adoption of a comprehensive risk management framework to guide decisions on prioritization and resource allocation at national level, with the involvement of both the public health and the security sectors (e.g. law enforcement, intelligence, military).

Exposure to pathogens is also possible in laboratory settings and as such poses a risk to the health of laboratory workers, the environment and the community. The significant increase in resources allocated to fight infectious diseases, including bioterrorism, in certain countries has lead to a dramatic increase in the number of laboratories in which dangerous pathogens are contained. Ensuring that biosafety and laboratory biosecurity standards and practices are implemented can significantly reduce the consequences of this type of risk.

Life science research and technology, such as biotechnology and genetic engineering, have the potential to significantly improve human health and well-being through, for example, the development of new therapeutics, vaccines and diagnostics as well as improve nutrition. However, the same technology could inadvertently or deliberately result in equally dramatic negative consequences. Norms and standards to manage these risks are being discussed by various stakeholders. If not well designed, however, norms and standards could either be ineffective or could hinder advancements in life science.

Risks associated with global health security are a collective responsibility that requires collective action. The IHR (WHO, 2005) are the public health framework for managing risks to global health security.

International Health Regulations (2005)

The IHR (WHO, 2005) were adopted by WHO Member States in May 2005 and entered into force on 15 June 2007. This legally-binding agreement significantly contributes to international public health security by providing a new framework for the coordination of the management of events that may constitute a public health emergency of international concern, and by improving the capacity of countries to assess and manage acute public health risks. Under the IHR (WHO, 2005) States Parties have two years in which to assess their capacity and develop national action plans, followed by a further three years to improve their capacities to meet a standard set of requirements in the areas of national surveillance and response and in designating airports, ports and certain ground crossings.

The objective of the IHR (WHO, 2005) is "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". A key requirement is for States Parties to develop capacity for surveillance and response to outbreaks. This is based on the principle that the most effective way to prevent international spread of diseases is to detect public health risks early and implement response actions rapidly, when the problem is still small. This can be achieved through early detection of unusual disease events by effective national surveillance, and the establishment of coordinated response mechanisms at all levels: local, national, regional and, when needed, international.

The IHR (WHO, 2005) contain six key elements: (i) they are wide-reaching in scope, encompassing any public health emergency of international concern as opposed to a limited list of diseases or group of diseases; (ii) they function as a decision-making instrument for the assessment and notification of events that may constitute a public health emergency of international concern; (iii) they are designed to be implemented through existing operational frameworks, with real-time

information-sharing and coordination that supports the legal framework; (iv) they set out a legal obligation for States Parties to meet core capacities for surveillance and response; (v) they retain a degree of flexibility for WHO to recommend measures that are commensurate with the level of risk and vulnerability; (vi) they are transparent in processes and based on sound technical advice, provided by the Emergency Committee and Review Committee, on which the WHO Director-General can draw in making recommendations for action.

Alert and Response Operations

In 1996, WHO introduced a systematic approach to the analysis of risks caused by outbreaks. Today the system has evolved enabling WHO to collect and analyse information on disease outbreaks and other events that pose risks to public health 24 hours a day, 7 days a week. This information is gathered from both official reports submitted by Member States and informal sources, such as news wires and other media. The information undergoes a process of risk assessment involving experts within the Organization including epidemiologists, disease-specific experts, entomologists and veterinarians. WHO then verifies the accuracy of the information, using its extended network of 147 Country Offices and six Regional Offices. Information is shared in accordance with WHO policy and the IHR (WHO, 2005). From January 2001 to June 2008, more than 2000 events of potential public health importance were processed by WHO. Naturally-occurring infectious diseases account for almost all of these events; some, however, were the result of accidental exposure to chemical agents or radiological materials. Information on the events brought to WHO attention is stored in an electronic event management system which records key information, decisions and actions taken by WHO and its partners.

WHO offers assistance to affected countries in the form of technical advice, supplies and, in some cases, by coordinating an international response. These operational responses draw technical resources from within the WHO system and from GOARN.

Global Outbreak Alert and Response Network

GOARN is a technical collaboration of 110 technical institutions, nongovernmental organizations (NGOs) and networks (GROAN, 2008). It represents a pooled resource for alert and response operations. Since 2000, GOARN has responded to 87 events, conducting response operations in 62 countries, with the involvement of some 50 partners and more than 500 experts.

GOARN plays a significant role protecting global health security by combating the international spread of diseases and ensuring that appropriate technical assistance reaches affected states rapidly.

GOARN has agreed standards for international epidemic response through the development of guiding principles to improve the coordination of international assistance in support of local efforts by GOARN partners. The Network has developed operational protocols to standardize epidemiological investigations, laboratory diagnosis, clinical management, research, communications, logistics support, security, evacuation and communication systems.

Laboratory biosafety and laboratory biosecurity

Laboratory biosafety and laboratory biosecurity practices are fundamental to public health. WHO has developed laboratory biosafety standards, included in the Laboratory Biosafety Manual (WHO, 2004), that are designed to improve and ensure the safety of operations in laboratories. The Manual provides recommendations on how to work safely, addresses users and policy-makers, and introduces laboratory biosecurity. Other WHO guidelines in this field include guidance for the transport of infectious substances (WHO, 2007b) and on laboratory biosafety (WHO, 2004).

WHO is implementing a series of awareness-raising workshops on laboratory biosafety, laboratory biosecurity and biosecurity of life science

(see below) across all WHO regions. Work is also progressing on a training-of-trainers manual to respond to the increased needs of countries for capacity building.

Biosecurity of life science

Life science research and biotechnology, including genetic engineering, synthetic biology, genomics and proteomics, have led to remarkable improvements in health. Developments in the field of drugs, vaccines and diagnostic tools have resulted in significant advances in the prevention, diagnosis and treatment of diseases. These advances, however, also present new challenges for public health. Measures to manage the potential risks associated with life science research could hinder further research and development. In addition, such risks could undermine public confidence in science. There is a need, therefore, for WHO to provide scientific advice for policy-making in this area, particularly given the varying levels of understanding and experience on this issue among WHO Member States.

WHO is raising awareness of and providing information on this issue by underlining the importance of research into life sciences. It also aims to provide guidance and develop tools for capacity-building to countries on risk management options for the accidental or potential misuse of the outputs of life science research – these being either the tangible products of research (e.g. biological agents) or the skills, methodology and knowledge associated with the research process.

Final considerations

An effective international preparedness and response coordination mechanism is essential in ensuring a safer future for the world. It calls for global cooperation, collaboration and investment. Such a mechanism requires a multisectoral approach with the involvement of governments, the private sector, academia, international organizations and civil society, all of whom have a stake in protecting global health security. The IHR

(WHO, 2005) represent a new tool for collective defence against the spectrum of risks to global health security in both enhancing and improving the core capacities within countries and in establishing a clear mandate and set of obligations for the WHO.

Acknowledgements

The activities briefly described in this paper are being implemented by teams of dedicated WHO staff working in Country Offices, Regional Offices and at Headquarters. The work is being undertaken by the Alert and Response Operations team, the International Health Regulations Coordination Programme, and the Biorisk Reduction for Dangerous Pathogens team of the Department of Epidemic and Pandemic Alert and Response, housed within the cluster of Health, Security and Environment of WHO Headquarters and their counterparts in the Regional and Country Offices. The author would like to acknowledge the contribution to this paper of Dr Cathy Roth, Team Coordinator, Biorisk Reduction for Dangerous Pathogens and Ms Penelope Andrea, Technical Officer (Writer), Epidemic and Pandemic Alert and Response.

REFERENCES

WHO. 2004. Laboratory biosafety manual, 3rd ed. Online available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/index.html; [Accessed May 2008].

WHO. 2005. International Heath Regulations. Online available at: http://www.who.int/csr/ihr/en/ [Accessed May 2008].

WHO. 2007a. The World Health Report 2007. A safer future: Global Public Health Security in the 21st Century. Online available at: http://www.who.int/whr/2007/whr07_en.pdf. [Accessed May 2008].

WHO. 2007b. Guidance on regulations for the Transport of Infectious Substances. Online available at: http://www.who.int/

csr/resources/publications/biosafety/
WHO_CDS_EPR_2007_2cc.pdf [Accessed 2008].
WHO. 2008. Global Outbreak Alert & Response Network. Online available at: http://www.who.int/csr/outbreaknetwork/en/ [Accessed May 2008].

BIOTECHNOLOGY AND BIORISK IN AFRICA

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The concepts of biosafety, biorisk and biosecurity have been well known for many years, but not in a security context. They have been used primarily in agriculture in terms of food production. In the case of biosafety, the concept of laboratory biosafety has been used to ensure a safe working environment for laboratory workers and to protect the environment and population in the vicinity of laboratories from dangerous pathogens and hazardous substances that are present in such laboratories.

The security and non-proliferation environment concentrated on preventing state-owned biological weapons programmes for many years. However, the September 11 terrorist attacks and, in particular, the anthrax letter incidents in the USA in 2001, caused the international perceptions to increasingly emphasise the threat of terrorism including with the use of weapons of mass destruction and terrorism involving biological agents (pathogens)—so-called bioterrorism. The result of this change in emphasis is that a different, security-oriented meaning was given to the concepts of biorisk and in particular biosecurity.

Whether this level of emphasis on the threat of bioterrorism, biorisk and biosecurity is always justified and universally applicable, has been the cause of intense debate over the last several years.

Purpose

The purpose of this paper is to consider biotechnology and biorisk in Africa and their relationship with laboratory biosafety and laboratory biosecurity from a security point of view.

Biotechnology

The focus of biotechnology in Africa is presently on agriculture, concentrating on improving food supply (Ndiritu, 2000). There is very little research and development conducted in other biotechnological fields such as genetic research, proteomics and bioinformatics. A few areas do exist where such research is conducted on a small scale. Production of bio-pharmaceuticals and pharmaceutical research is concentrated in North Africa and also conducted on a small scale (Ndiritu, 2000; Juma and Serageldin, 2007; Egwang, 2001; African Union, 2006; Wambugu, 2003).

From the literature it is clear that the needs and drive for biotechnology in Africa are different from those in industrialised countries. The primary drive in Africa is aimed at improving and sustaining food production (Ndiritu, 2000).

There are increasing efforts to add to existing biotechnological research and development in Africa, but they are still hampered by factors such as a wide enough knowledge base to sustain such research, funding and the importance attached by governments to such research. There is also very little private investment in biotechnology other than agriculture (Juma and Serageldin, 2007; African Union 2006).

Therefore, there is very little capacity for the diversion of biotechnology to the illegal use for biological weapons development in Africa.

Biorisk

The threat posed by biological agents (infectious disease) to a population can originate in nature or through human actions, which include the following activities:

a. Unintentional exposure to pathogens due to non-compliance with biosafety measures, which can range from individual exposure inside a laboratory, accidental release of pathogens from a laboratory in various ways and secondary contamination from other sources such as medical waste;

b. The use of pathogens that were illegally obtained from a laboratory or other source. The prevention of illegally obtaining pathogens from laboratories falls in the ambit of biosecurity; and

c. Deliberate development of biological weapons by states or non-state actors.

In the consideration of the biorisk in Africa all these factors will be discussed shortly.
While it is a well known fact that Malaria, TB and HIV/AIDS are the major causes of death in Africa; none of these diseases is considered to be of concern in terms of their use as a weapon. Furthermore, the vast majority of diseases of concern are naturally occurring in Africa. Some examples include:

i. Anthrax: Anthrax is an endemic animal disease in most African countries and there are regular cases of animal anthrax. Veterinarians work with anthrax all over the continent in and outside diagnostic laboratories. Human cases of skin and enteric anthrax are also common. Animal vaccines against anthrax are produced in Africa, but not human vaccines. Most defence forces in Africa do not consider it necessary to vaccinate their soldiers against anthrax.

ii **Plague**: Plague still occurs in a number of African states.
iii. **Haemorrhagic Fevers:** Most Haemorrhagic fevers are endemic in various African countries and there are regular cases of which the majority are not managed in high containment conditions.
iv. **Brucellosis**: Brucellosis is an endemic animal disease and cases occur frequently.
v. **Cholera:** It is well known that cholera is endemic in many African states.
vi. **Foot and Mouth Disease (FMD):** FMD is also endemic in many African states and outbreaks are not unusual.

It is clear that the majority of these diseases are common and have to be managed in many African states; therefore, the pathogens in their natural form are not difficult to obtain, but as such do not pose a major threat.

a) Unintentional Exposure

Officially verified statistics on laboratory accidents of any nature are not readily available. However, it can be safely assumed that the vast majority, if not all major incidents involving biological agents over the last five years, were due to unintentional exposure. It would also be safe to say that such cases were the result of not adhering to safety requirements and procedures.

Although there are not many laboratories that work with highly dangerous pathogens in Africa and given that many of these diseases named above are endemic to Africa, the potential for laboratory accidents is high due to inadequate safety measures and/or the lack of implementation of such measures.

Contaminated waste from hospitals and clinics can also be a source of unintentional exposure to pathogens if the management of such waste is not of a high standard.

b) Illegal Obtaining of Pathogens

Currently, the primary concern with regard to biological weapons is the illegal obtaining of highly dangerous pathogens by terrorists and/or criminals for use as weapons. A variety of scenarios on how this could be done exist, but that falls outside the scope of this paper. Pathogens can be obtained illegally from different types of laboratories:

i. **Diagnostic laboratories**: There are examples of pathogens (not lethal) that have been stolen from diagnostic laboratories; however, there are no known incidents in Africa. The pathogens obtained from such laboratories will be in their natural form since they will be obtained from clinical samples. Use of pathogens obtained in this manner would have similar results as the use of pathogens obtained from nature or hospital waste.
ii. **Research Laboratories:** Research laboratories, particularly laboratories that do research on dangerous pathogens may be targeted to obtain dangerous pathogens. As pointed out in the section on biotechnology, the numbers of laboratories of this nature are limited in Africa and therefore the potential of theft from such laboratories is also limited.
iii. **Biodefence Laboratories**: Biodefence, particularly those working on pathogens will due to their nature be targets for theft. However, again due to their nature such laboratories should inherently have high levels of security. According to the annual Confidence Building Measure Declarations by States Party to the Biological Weapons Convention to the UN of the last five years, there is only one state involved in Biodefence research in Africa, but it does no research with pathogens. Although there may be one or two more states involved in such research, the risk of such laboratories being potential sources of pathogens is also quite low.

c) Deliberate development of biological weapons by states or non-state actors

Most of the international instruments have a mention prohibiting the development of biological weapons. The Biological and Toxin Weapons convention prohibits the development, production, stockpiling, acquisition and retention of Biological Weapons.

Conclusion

A reasonable conclusion that can be drawn from the discussion is that the primary biorisk for Africa lies in nature and all the endemic diseases occurring in Africa. Furthermore, it is also clear that the need for proper biosafety measures in laboratories and in other spheres of public and animal health as well as the training and emphasis on scientists to work safely under all circumstances is paramount.

Therefore, it is very important that Africa spends its resources where the biggest difference can be achieved and that is in the following areas:

i. Training of scientists, health care and veterinary workers to work safely under all conditions, including safety in existing curriculum at higher science education level can go a long way in solving this need cost effectively.
ii. Improving the safety and good laboratory practices. In this regard, it must be emphasised that the answer is not the construction of containment laboratories, because experience elsewhere in the world has shown that safety does not necessarily lie in buildings and structures but more in the dedicated application of safety measures and that safety practices become second nature to all involved; and
iii. Allocating additional resources and efforts to improve waste management.

REFERENCES

Egwang, T.G. 2001. Biotechnology Issues in Africa. *Electronic Journal of Biotechnology.* Vol 4, No 3 2001.

Juma, Calestous and Serageldin, Ismail. 2007. Putting Biotechnology to Economic Use. *Business Daily* (Kenya) Nov 13, 2007.

NEPAD and AU. 2006. Freedom to innovate: Biotechnology in Africa's development. Draft Report of the High-Level African Panel on Modern Biotechnology of the African Union (AU) and the New Partnership for Africa's Development (NEPAD). July 14, 2006.

Ndiritu, C.G. 2000. Biotechnology in Africa: Why the Controversy? Agricultural Biotechnology and the Poor: An International Conference on Biotechnology. pp.110 – 114.

Statement of Dr. Florence Wambugu (President, A Harvest Biotech Foundation International Nairobi, Kenya). 2003. Hearing on "Review of Artificial Barriers to United States Agricultural Trade and Foreign Food Assistance". March 26, 2003.

BIOSECURITY: THE WEB OF PREVENTION

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The threat from disease can conceptually be divided into three elements:

1. Natural disease;
2. Inadvertently caused disease; and
3. Deliberately caused disease.

We attempt to deal with natural disease by public health measures in the first place and we attempt to prevent inadvertently caused disease by careful biosafety measures.

The threat of deliberately caused disease comes from the possibility of the hostile use of biological agents in biowarfare and bioterrorism and,

as we have come increasingly to realise, from the possible future misuse of the results of benignly-intended research in the biotechnology revolution.

Despite the series of large-scale, state-level, offensive biological weapons programmes during the twentieth century, this threat was largely forgotten during the nuclear-dominated East-West Cold War. However, at the end of the Cold War, in the early 1990s, this situation changed. As Pearson (1993) noted:

> ...The recent changes in the world scene and increased awareness of the potential impact of Chemical and Biological (CB) weapons give a new urgency and incentive to devising a strategy that complements arms control with a range of other measures to form a web of deterrence such that an evader or potential evader will judge that acquisition of chemical or biological weapons would be prohibitively expensive, of doubtful military value, and carry substantial risk of detection that would make it politically unacceptable...

Pearson therefore proposed a web of deterrence consisting of the following elements:

- Comprehensive, verifiable, and global arms control;
- Broad CB export monitoring and controls;
- Effective CB defensive and protective measures; and
- A range of determined and effective national and international responses to CB acquisition and/or use.

Such policies of deterrence were clearly aimed at preventing state-level offensive biological (and chemical) weapons programmes.

Since the early 1990s, as the problem of bioterrorism and the dangers of dual-use have become more prominent, increasing emphasis has been placed on proper implementation of the Biological and Toxin

Weapons Convention (BTWC) in States Parties and on better control of the potential misuse of benignly-intended civil biotechnology. This shift of emphasis was clearly evident in the International Committee of the Red Cross Appeal of 2002 which suggested, for example, that the scientific community (ICRC, 2002):

....scrutinize all research with potentially dangerous consequences and ... ensure it is submitted to rigorous and independent peer review.

Thus the original idea of a web of deterrence against State-offensive biological weapons programmes has evolved into the idea of a web of prevention against all aspects of misuse. But the original idea of identifying points of potential policy intervention and effective policies at these points remains central.

Within the inter-sessional meetings of the BTWC, considerable attention has been paid to the in-depth implementation of the Convention under Article IV. This in-depth implementation has clearly been seen to involve codes of conduct and appropriate education for life scientists.

The emphasis on education and codes of conduct was evident in two paragraphs (14 and 15) of the *Final Declaration* of the Sixth BTWC Review Conference in 2006 (UN, 2006) and will again be the focus of attention at the 2008 inter-sessional meeting. There is every reason to devise a new website in order to provide an integrated overview of all the policy intervention points and potential policy options in the new idea of a web of prevention, particularly as a resource in support of new educational modules for life scientists.

REFERENCES

International Committee of the Red Cross. 2002. Appeal on Biotechnology, Weapons and Humanity. Available at: www.icrc.org.

Pearson, G. S. 1993. Prospects for Chemical and Biological Arms Control: The Web of Deterrence. *The Washington Quarterly*, Spring, 145-162.

United Nations. 2006. Sixth Review Conference of the States Party to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) Weapons and on their Destruction. Final Document, BWC/CONF.VI/6.

2
Biosafety

OVERVIEW

Microbiology laboratories around the world are involved in culturing micro-organisms as they perform research, making them an essential component in the battle against infectious diseases. Such laboratories must therefore maintain vigilant biosafety and biosecurity procedures to protect the public from unintentional or even intentional spillage[4]. Incidences of accidental and intentional spillage do exist and this calls for adherence to strict biosafety practices as well as following procedures that laboratories are legally mandated to follow—such as those guidelines outlined by the 1972 Biological and Toxins Weapons Convention (BTWC), UN Cartagena Protocol on Biosafety and Conservation of Biological Diversity, and the World Federation of Culture Collections (WFCC). Ultimately, individual workers are responsible for both individual and colleague safety (responsible conduct of scientists). Regulatory oversight measures by governments are also needed. Overall, to achieve biosecurity, a multi-pronged approach is needed that features both legally binding and ethical behavioural components. This requires joint action by national science academies, governments, and the scientific community. The paper on biorisk outlines the elements that are required to implement a robust biorisk management programme.

[4] Intentional spillage implies a situation where an individual knowingly spills toxins or dangerous pathogens, this can also be considered as biosecurity.

A sound biorisk management programme is critical for infectious disease laboratories and, to be effective, the programme must have three key interrelated elements: planning, implementation and oversight. A biosafety and biosecurity risk assessment should be the principal planning tool that guides management's implementation and oversight of laboratory biosafety and biosecurity, including the determination of training needs. The risk assessment process can help management answer some critical questions: How does a laboratory determine which training is required for whom? What level of oversight is appropriate? How are limited resources allocated to address the laboratory biorisks? Also discussed is the need to develop national biosafety systems where the focus is on setting up national biosafety systems to manage modern gene-based biotechnology (genetic modification). Why should we have a national biosafety system? Environmental, human health, biodiversity, socioeconomic and ethical issues are a requirement under the Cartagena Protocol on Biosafety. National biosafety systems are meant to: (a) Establish science-based, holistic and integrated, efficient, transparent and participatory administrative and decision making system so that a country can benefit from modern biotechnology while avoiding or minimizing the possible environmental, health and socio-economic risks; and (b) Ensure that the research, development, handling, trans-boundary movement, transit, use, release and management of genetically modified products are undertaken in a manner that prevents or reduces risks to human and animal health, biological diversity and the environment. Components of a national biosafety system include: national policies related to biosafety, regulatory regime, administrative and decision mechanism, monitoring mechanisms, mechanisms for public awareness, education and participation, scientific knowledge base, skills, and capacity. Most African countries, despite having ratified the Cartagena Protocol, do not have functional biosafety systems. It can therefore be challenging to develop national biosafety systems.

BIOSAFETY AND BIOSECURITY IN MICROBIOLOGICAL LABORATORIES

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Introduction

Every day dangerous pathogens are isolated from infected humans and animals in clinical and veterinary microbiology laboratories, including numerous such laboratories in Africa. Microbiologists around the world culture microorganisms as they perform the research needed to discover and develop vaccines, therapeutics, and diagnostics to combat infectious diseases. Cultures of pathogenic microorganisms are maintained in collections housed in Biological Resource Centres associated with these clinical and research laboratories. These activities make microbiological laboratories essential in the battle against infectious diseases. But, microbiology laboratories must exercise vigilant biosafety and biosecurity procedures to protect laboratory workers and the general public from infectious diseases.

Accidental Releases and Biosafety

Unfortunately there have been a number of biosafety lapses at microbiology laboratories that have resulted in the infection of laboratory workers and the broader public. This was apparent during the SARS outbreak when laboratory workers became infected and at least in one case spread the disease to others. These accidental releases could have been prevented by adherence to strict biosafety practices. They also highlight the importance of medical screening of those working with dangerous pathogens and having plans for isolating those individuals should they become infected. Guidance for effective biosafety practices, including the appropriate levels for physical containment, is provided by the World Health Organization (WHO, 2008) and national governmental bodies such as the Centres for Disease Control and Prevention (CDC, 2008). The actions of the laboratory director and

the maintenance of an up-to-date biosafety manual to which all personnel adhere are critical for ensuring laboratory biosafety. Ultimately, however, individual workers are responsible for their own safety and that of their colleagues.

Biosecurity

Going beyond biosafety, biosecurity should be viewed as a critical focus of all microbiological research and clinical diagnostic laboratories. Taken together biosafety and biosecurity encompass all of the activities aimed at preventing microbial infections, including those aimed at preventing laboratory workers from becoming infected and those aimed at preventing the release of pathogens from microbiological laboratories. Depending upon the definition one chooses, biosecurity may be seen as an extension of biosafety aimed at keeping pathogenic organisms in the laboratory and out of the hands of terrorists—a view generally held in the United States and supported by the World Health Organization, or biosecurity may be viewed as preventing exposure to harmful organisms—a view held by countries such as New Zealand and Australia. From a microbiologist's perspective, it is appropriate to adopt an overarching definition of biosecurity as the protection against exposure to microorganisms that could cause harm regardless of whether that involves naturally occurring infectious agents or the intentional misuse of microorganisms as weapons. As such, biosecurity in microbiological laboratories should encompass all of the activities aimed at preventing microbial infections, including those aimed at preventing laboratory workers from becoming infected (biosafety practices) and those aimed at preventing the release of pathogens from microbiological laboratories and biological resource centres (often narrowly defined as biosecurity practices aimed at preventing the acquisition of dangerous biological agents by terrorists). Adopting and adhering to such an overarching concept of biosecurity should be viewed as forming the basis for the critical operating principles of all microbiological research and clinical diagnostic laboratories.

For achieving effective biosecurity, mutually reinforcing strands are necessary, including some that are legally mandated and some that involve responsible conduct of scientists. According to Article III of

the Biological and Toxins Weapons Convention, there is a legally binding obligation for the States Parties not to transfer to any recipient whatsoever, directly or indirectly, and not to assist, encourage, or induce States, groups of States or international organizations to manufacture or otherwise acquire any of the biological agents prohibited by Article I of the Convention. Resolution 1540 under Chapter VII of the Charter of the United Nations also makes it legally binding for all UN member states to adopt domestic measures to prevent the proliferation of biological weapons, their means of delivery and related materials, including by accounting for and physically protecting such items; establishing and maintaining effective border controls and law enforcement measures; and reviewing and maintaining national export and trans-shipment controls (with appropriate criminal or civil penalties).

Biosafety and Biosecurity Measures

The World Health Organization (WHO) has recognized that there is a need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm people, livestock, agriculture or the environment. WHO has said that national standards should be developed that recognize and address the ongoing responsibility of countries and institutions to protect specimens, pathogens and toxins from misuse. It is the view of the WHO that security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices, and that biosecurity should be implemented so as not to interfere with the critical research and diagnostic activities of microbiology laboratories. In fact the WHO considers effective biosafety practices to be the very foundation of laboratory biosecurity activities and that assessment of the suitability of personnel, security-specific training and rigorous adherence to pathogen protection procedures are reasonable means of enhancing laboratory biosecurity.

The issue of security and legitimacy of exchanges, including how to deny biological resources from those who would misuse them for bio warfare or bioterrorism, has become a critical issue for global security. The potential acquisiton of cultures from biological resource centres

for a biological weapons programme raised issues regarding the need for heightened control of exports of pathogenic microorganisms and the scrutiny of international exchanges of microbial cultures. The belief that the anthrax attacks of Fall 2001 were carried out by a US scientist and that the bacteria came from a US laboratory further raised concerns about biosecurity of culture collections and who should be given access to cultures of dangerous pathogens.

Given the global distribution of pathogens that could be used for bioterrorism or biowarfare, it is critical that microbiologists universally support appropriate oversight measures to ensure that individuals who are provided access to agents that could be used for acts of bioterrorism are deemed trustworthy and that the agents are protected from potential misuse. However, most efforts to restrict the distribution of potential biothreat agents, such as those engendered by the Biological and Toxins Weapons Convention and UN Resolution 1540, rest with national legislation and regulations, rather than as part of a harmonized global effort. Regardless of where a microbiologist is working, he or she should have an ethical responsibility to seek to protect the life sciences from becoming the death sciences, which includes trying to prevent terrorists from acquiring dangerous pathogens that could be used to do harm.

Laws and mandatory regulations in some countries, such as the Select Agent Regulations in the United States, now restrict who is allowed to have access to certain biological threat agents; various government agencies have become responsible for ensuring accurate tracking of the acquisition, transfer, and possession of select agents and also for establishing safeguards and security procedures to be followed by institutions in possession of those agents. Many nations also have mandatory export and import regulations that control exchanges of pathogenic micro-organisms and the equipment that could be used to make biological weapons. The Australia Group provides guidance on what is considered to be potential dual-use agents and equipment where export controls should be imposed to deter the development of biological weapons. Recognizing that “particular attention needs to be given to the containment and security aspects of strains which are potentially

harmful to man, animals or crops," the World Federation of Culture Collections (WFCC) has produced guidelines for its members which are available via the World Data Centre for Microorganisms (WDCM) website. Given the importance of biological resources for the advancement of microbiology and biotechnology, the Organization of Economic Cooperation and Development also has undertaken a project to try to enhance the legitimate exchange of resources and related molecular data that could further the development of medical cures and other benefits from research in the life sciences. The initial thrust of this initiative was the free exchange of biological resources through a global network of BRCs operating within legal and ethical boundaries. Increasingly, there has been international concern about the exchanges of microbial agents that can be used as bio-weapons and how BRCs can be secured. Thus, a duality has developed in the international dialogue about the exchange of cultures of micro-organisms and of data that could be misused—openness on the one hand versus security on the other. To help protect against bioterrorism, the WHO has expanded its guidance for nations around the world to include biological security issues, In essence, this has involved declaring that the world's collections of microorganisms and microbiological laboratories must not become sources of biothreat agents for terrorists.

Various national science academies and professional societies have also been considering how to protect the life sciences against misuse. The US National Academy of Sciences report by the Fink Committee, *Biotechnology Research in an Age of Terrorism, Confronting the Dual Use Dilemma* (US National Academies, 2004), sought to develop an effective way of helping to protect the life sciences scientific community against the potential misuse of biological materials and information. The Committee recommended a bottom-up approach aimed at helping to reduce the threat of misuse of the life sciences to augment government regulations for biosafety and laboratory pathogen biosecurity. This places great responsibility on the scientific community to ensure that its activities first do no harm. The report emphasized the need for international efforts to combat the threat of bioterrorism. Indeed, a globalized effort is needed to protect against infectious diseases.

Conclusion

Biosafety and biosecurity practices are essential at all microbiological research and diagnostic laboratories. In today's era of terrorism and emerging infectious diseases, the issue of security and legitimacy of possession of pathogenic micro-organisms, including how to deny biological resources from those who would misuse them for biowarfare or bioterrorism, is critical for global security. International agreement on what is of real concern is needed so that harmonized steps can be taken to prevent terrorists from acquiring biothreat agents. It is critical that all nations adopt appropriate regulatory oversight measures to ensure that individuals who are provided access to agents that could be used for acts of bioterrorism are deemed trustworthy and that the agents are protected from potential misuse.

To achieve biosecurity, we need a multi-pronged approach with both legally binding and ethical behavioral components. We should begin by defining better the sphere of concern. If we are to protect against bioterrorism, microbiological laboratories and individual microbiologists will need to accept new scrutiny and regulatory requirements that may constrain their abilities to supply certain micro-organisms to research, educational, and domestic laboratories. Governments, scientific organizations, such as the world's national science academies, and individual scientists in all countries will have to contribute to the efforts to protect against bioterrorism and the ills of infectious diseases. Within the scientific community a global culture of responsible conduct must be developed. In addition, advice needs to be provided to governments as they seek to define the sphere of concern and to formulate effective measures that will enhance security while permitting the advancement of science and the battle against infectious diseases. The end result must be the universal practice of biosafety and biosecurity in microbiological laboratories worldwide

REFERENCES

CDC. 2008. Biosafety. Available at: http://www.cdc.gov/od/ohs/biosfty/biosfty.htm

US National Academies. 2004. Biotechnology Research in an Age of Terrorism, Confronting the Dual Use Dilemma. National Academies Press: Washington, DC.

WHO. 2008. Laboratory Biosafety Manual (third Edition). Available at: http;//www.who.int/csr/ resources/ publications/biosafety/en/ Biosafety 7. pdf.

BUILDING A SOLID FOUNDATION FOR IMPLEMENTING LABORATORY BIOSAFETY AND BIOSECURITY

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By the very nature of their missions, infectious disease institutions must manage the risks associated with biological materials in their laboratories. These materials could be the source of accidental and/or deliberate (malicious) infections to the staff or the broader community. A failure in laboratory biosafety or biosecurity may affect the staff and community, and may jeopardize the institution's operations. Laboratory biosafety aims to keep the worker and environment safe from accidental exposure while laboratory biosecurity seeks to keep the valuable biological materials secure from intentional theft or misuse. There are many examples of inadequate programme management resulting in safety or security incidents at bioscience facilities. For example, the United Kingdom recently suffered an outbreak of Foot and Mouth Disease

[5] SAND Number: 2008-1137C. Sandia is a multiprogramme laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000. This paper would not have been possible without the CEN Workshop process, countless discussions with participants, and especially the two co-chairs, Dr. Stefan Wagener and Dr. Gary Burns. I would also like to gratefully acknowledge the many individuals who have been involved in the development of the training courses cited in this paper.

virus. This was most likely caused by failures in a laboratory's waste decontamination system due to neglected maintenance and repairs (Enserink, 2007). In the United States, regulators shut down large sections of the infectious disease research programme at Texas A&M University's after it failed to properly report several laboratory incidents (*Dallas News*, 2007). Professor Thomas Butler, a renowned bacteriologist, spent 19 months in jail awaiting trial after 30 vials of *Yesinia pestis* went missing from his laboratory (Plain Dealer, 2006). In 2003 and 2004, there were three separate laboratory-acquired infections of SARS at BSL3 and BSL4 laboratories in Singapore, Taipei, and Beijing; one incident led to multiple infections in the community. A subsequent investigation by a World Health Organization (WHO) team determined that poor programme management was the root cause in all of these cases (WHO, 2005). To minimize the likelihood of such problems, bioscience facilities must allocate the needed resources, develop guidelines and operating procedures, train their personnel in these institutional protocols, and provide adequate oversight of activities. All of these decisions should be influenced by regular risk assessments.

The nature and scale of these risks at an institution should be the determining factors for the scope of the biorisk management programme (laboratory biosafety and biosecurity), but regardless of size, there are commonalities that stretch across all of these programmes: recruiting and retaining qualified individuals, training, laboratory work practices, (e.g. disinfection, waste handling, material control and accountability), personal protective equipment, medical surveillance, maintenance, access controls, self-assessments, documentation, corrective actions, reporting requirements, and incident response plans, to name a few. To avoid inadequately addressing any of these elements, an institution should ensure that it has a cohesive bio risk management programme for mitigating laboratory biorisks; a management system can be a useful framework. One of the primary goals of a management system is to help an organization continually strive for improvement. ISO 9001:2000 (a quality management system), ISO 14001:2004 (an environmental management system), and OHSAS 18001:2007 (an occupational health and safety management system) are all examples of management

systems that have been implemented at laboratories, but none of these are specific to managing biorisks. However, a new management system standard should be useful for bioscience facilities seeking to enhance their biorisk management programmes. In 2007, biosafety and biosecurity experts developed a voluntary management standard explicitly for managing the biorisks in institutions that handle biological agents and/or toxins, regardless of the type or size of institute or the specific biological materials (CEN, 2008). A risk-based approach lies at the heart of that standard.

Planning

Planning is the first step of a management system, and risk assessment should be the primary planning and resource allocation tool for managing biorisks. First, the biohazards are identified and characterized. Next, the biological agents are assessed on their properties, such as pathogenicity, virulence, host range, routes of transmission, and environmental stability. Laboratory procedures are then evaluated for the potential to cause accidental exposure to the agent (e.g. spill, generation of an aerosol, needle stick) or release from containment. The local threat environment is characterized to help assess the likelihood that the facility will be targeted by those wishing to do harm. Gaps in existing biosafety and biosecurity measures are evaluated for scenarios that pair the potential for accidental or deliberate exposure or release with the potential consequences for the specific biological agent. Once these gaps are identified, management can prioritize efforts to address the most significant gaps. Unless the biohazard is eliminated, some level of risk will remain; no biorisk management programme can protect against every conceivable adverse scenario. The risk assessment process helps management ensure that the biosafety and biosecurity risk mitigation measures and associated costs are proportional to the risks. Risk assessment provides a foundation for allocating programme resources among engineered, administrative, and procedural controls to mitigate the biorisks.

Implementation

Assigning roles and responsibilities is a critical step in building a sustainable biorisk management programme. Regardless of programme size, the institution should assign oversight responsibility to a biorisk manager (traditionally the biosafety officer). This individual should be knowledgeable in biosafety and biosecurity and they will oversee the implementation of biorisk mitigation measures; advise and assist with the reporting, investigation, and follow-up of any incidents; oversee the development and implementation of relevant training; and ensure regulatory compliance. The principal investigators or other scientific managers should be directly responsible for managing the biorisks associated with their specific laboratory operations. The biorisk manager and scientific manager should jointly conduct the risk assessments. An institution should establish a biorisk management committee with a cross-section of expertise to act as an independent review group. This committee should be tasked with approving protocols for new work, reviewing incident reports, and developing institutional biorisk policies. Ultimately, top management is responsible for the institution's biorisk management programme.

Before individuals begin to work with biohazards, they need training. Training programmes can be viewed as a ladder of knowledge and skills. There is basic awareness-raising, knowledge of laboratory biosafety and biosecurity fundamentals, hands-on learning of best practices, advanced training on best practices, facility-specific training, and task-specific training. Typical training programmes convey awareness and fundamentals through a series of PowerPoint presentations while the latter topics are learned in an informal mentoring arrangement between a new employee and a more knowledgeable, senior staff member.

Although PowerPoint presentations and informal mentoring can be valuable in the right setting, more interactive, structured training on specific learning objectives is necessary to help individuals climb the ladder of knowledge and skills. There are a range of new training

initiatives making this shift. The American Biological Safety Association draws on the depths of their professional expertise to incorporate realistic case studies and lessons learned into a week-long training course on the Principles and Practices of Biosafety (www.absa.org/contactivities.html). The World Health Organization (WHO), in partnership with the U.S. National Institutes of Health (NIH), piloted a two-week training course based on the third edition of the WHO laboratory biosafety manual. This course utilizes lectures, case studies, and hands-on laboratory exercises. NIH also runs a two year Biosafety and Biocontainment Fellowship Programme, which trains future biosafety officers through a combination of instruction and a structured mentorship (www.nbbtp.org). The International Biological Threat Reduction Programme at Sandia National Laboratories has developed a week-long training programme on Controlling Laboratory Biorisks (www.biosecurity.sandia.gov). This program focuses on the integration of laboratory biosafety and biosecurity with lectures, case studies, guided discussions, and hands-on laboratory activities.

Two relatively new programs offer excellent training for those individuals seeking instruction on high containment laboratory activities. Emory University conducts a Science and Safety Training Program, which emphasizes knowledge and practice of laboratory activities for BSL3 and BSL4 laboratories (www.sph.emory.edu/CPHPR/biosafetytraining). The Canadian Science Centre for Human and Animal Health gives participants the opportunity to work in the special containment and facility support areas (BSL3 and BSL4) at their annual International High Containment Biosafety Workshop (www.biosafety.ca/home.html).

The collective impact of these programs and other new training initiatives is still to be determined, but, undoubtedly, they are shifting the paradigm of training for biorisk managers and laboratory personnel. All of these training programmes give their students a solid foundation, but they are not sufficient. Laboratory workers still require facility-specific and task-specific training prior to beginning work with biohazards and at regular intervals for retraining. The biorisk manager or other appropriate

manager should establish an institutional training programme. This programme should define the training needs, specify required training and refresher training, and measure its effectiveness. The risk assessment should be a key tool in developing the institutional biorisk training programme.

Oversight

The overarching goal of any biorisk programme should be continuous improvement. First, the programme must document its current biorisk activities. Documentation will include risk assessments, biorisk manuals, standard operating manuals, organizational charts, maintenance plans, equipment certifications, inventory records, and so forth. Documents should be reviewed and updated at regular intervals and after any incidents. Furthermore, risk assessments need to be reviewed after any changes to the institution's programme or threat environment. Oversight of the programme should be formalized through regular audits to assess effectiveness and evaluate areas for improvement. The frequency of these audits should be based on the risks. They should consist of both internal self-assessments and external third-party assessments that provide an independent review. All audit findings should be documented in a report that specifies corrective actions, assigns responsible individuals to each action item, and identifies an expected completion date for each item. Then the biorisk manager needs to follow up and verify the timely completion of the corrective actions. Finally, top management should review the biorisk management programme at least annually to explore opportunities for improvement. The end result of such a review should specifically address the suitability of the current risk assessments and appropriateness of the existing resource allocations.

Conclusion

An effective biorisk management programme must be based on the specific risks at the institution. The risk assessment then drives allocation of resources, the implementation of the risk mitigation measures, training requirements, level of programme management, and degree of oversight.

Biorisk management systems can be an effective tool to help institutions create safe and secure laboratories, helping to maintain community confidence in their operations.

REFERENCES

CEN. 2008. Laboratory Biorisk Management Standard, CEN Workshop Agreement 15793, February 2008

Dallas Morning News. 2007. CDC reprimands Texas A&M over lab Safety. Available at: http://www.dallasnews.com/sharedcontent/dws/dn/latestnews/stories/090507dntexcdc.9f66c8cc.html

Emory University, available at: www.sph.emory.edu/CPHPR/biosafetytraining

International Biological Threat Reduction. Available at:www.biosecurity.sandia.gov (accessed 14 May 2008)

International Centre for Infectious Diseases, 7th International High Containment Biosafety Workshop, Available at: http://www.biosafety.ca/home.html (accessed 14th May 2008)

Enserink M. 2007. Biosecurity: Reports blame animal health lab in Foot and Mouth Whodunit in Science, Volume 317. p. 1486.

National Biosafety and Biocontainment Training Programme. Available at www.nbbtp.org (accessed 14 May 2008)

Plain Dealer. 2006. Plagued by Fear, Available at: http://www.cleveland.com/plague

WHO.2005. Futoshi Hasebe, Western Pacific Regional Office, conference presentation, REDI Centre, International Laboratory Biosafety and Biosecurity Meeting, Singapore, 7-8 April 2005.

DEVELOPING NATIONAL BIOSAFETY SYSTEMS

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As a scientific discipline biosafety consists of practices to control, prevent and minimize exposure of humans and the environment to biological hazards (Hill et al 2004; Goldstein, et. al. 2005) as well as preventing and managing hazards associated with pathogenic microbes or toxins of biological origin (Grant and Kerr, 2003). This discipline also covers preventing and managing the biological risks associated with "modern gene-based biotechnology"; assessment of potential risks or hazards of biological nature and their impact on human health and environment, as well as safety of food from pathogens, allergens and biological toxins. Preparedness to deal with biological weapons, bioterrorism, biosecurity and biodefence issues; laws and regulations addressing safe use of biotechnology are also components of biosafety (Schoch-Spana, 2004; Guillemin and Schoch-Spana, 2005).

The focus of this paper will be on setting up national biosafety system to manage modern gene-based biotechnology also known as genetic modification or genetic engineering GE technology. The products are referred to as genetically engineered (GE), genetically modified (GM) or as living modified (LM) organisms. The Convention on Biological Diversity (CBD, 1992) defines biotechnology as any technological innovation that uses biological systems, living organisms, or derivatives thereof, to make or modify products for specific use. Hence GE technology is a subset of biotechnology and is where a gene or genes has/have been artificially inserted in an organism for a specific purpose. The GE technology is cutting-edge science and is relatively new, so not many people, including some biological scientists are conversant with its application. This technology is also controversial and is regulated based on biosafety principles. Biosafety in this context encompasses a set of measures and procedures for minimizing potential risks that biotechnology can pose to the environment and human health.

International Agreements Relating to Biosafety

Developing national biosafety systems stems from international agreements that countries have ratified under United Nations Conventions. Two international agreements have a direct bearing on developing a national biosafety system. The UN Convention of Biological Diversity (1992) established the Cartagena Protocol on Biosafety (CPB) (2000) to address biosafety management at a global level. This protocol came into force on 11 September 2003 and to-date 143 countries including 40 African states have ratified this protocol. The Cartagena Protocol was developed to help countries to ensure an adequate level of protection in the field of safe transfer handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health and specifically focusing on trans-boundary movement. The protocol spells out procedures for regulating living modified organisms (LMOs) to be intentionally introduced into the environment and for LMOs to be used directly as food, feed or for processing. This protocol provides for legislation in the event of trans-boundary movement and advances risk assessment, risk management and risk communication strategies for member countries. While the CPB provides a basis for the biosafety system, countries have an obligation to develop national systems that comply with international obligations while taking into account national environments and priorities. The biosafety framework should establish: regulatory, administrative and decision-making systems that include risk assessment and risk management and the mechanism for public participation and information.

The second agreement, CODEX Alimentarius, is an international forum established jointly by the United Nation's Food and Agriculture Organization (FAO) and World Health Organisation (WHO). The mandate of CODEX is to develop guidelines on food and feed derived from GE products and to set international standards on food safety and control (FAO/WHO 1963). Countries that are signatories to this agreement follow such guidelines.

At the continental level, an African Model Law on Safety in Biotechnology, finalised in May 2001, was endorsed by the Organisation of African Unity Assembly of Heads of State and Government in July 2003 in anticipation of the entry into force of the Cartagena Protocol. The Model Law is an attempt to harmonize existing and future biosafety legislation in Africa. It provides a comprehensive framework of biosafety regulations specifically designed to protect Africa's biodiversity, environment and the health of its people from the risks posed by GMOs. The original version was revised in 2007 (AU, 2007).

Justification for a National Biosafety System

Modern biotechnology is an emerging novel tool in research application and development with potentials in improving human and animal health, industrial and agricultural production as well as environmental protection. The biotech industry is growing very fast. For example during 2007 over 100 million hectares of transgenic crops were grown involving over 10 million farmers indicating an unprecedented 60-fold increase in production between 1996 and 2006, making it the fastest adopted crop technology in recent history. In 2006, the global market value of biotech crops (genetically modified) was estimated at $6.15 billion representing 16per cent of the $38.5 billion global crop protection market in 2006 and 21per cent of the ~$30 billion 2006 global commercial seed market (James, 2007). However, the development and applications of modern biotechnology have been associated with both opportunities and risks. Concerns raised against modern biotechnology include environmental; human health; biodiversity; and socio-economic and ethical issues. These and other concerns have raised the need of putting in place National Biosafety regulatory systems. This obligation also emerged as one of the priorities following adoption of the Cartagena Protocol on Biosafety.

Many reasons can be advanced for regulating GE products; but the major ones include: the need to examine broadly potential risks and benefits from the introduction of a particular product in the country; analysis of direct benefits; and costs of adopting and not adopting the technology. It is also important to identify which areas contribute more

overall to safety and net benefits in order to focus investments in the regulatory system. Further, it is necessary to know what can happen if regulating in general or if a particular product is ignored by a country. Many technologies pose a tension between safety and innovation. When innovation is a path to address poverty and promote sustainable growth, it may be difficult to curtail its progress but governments and technology developers have a responsibility to employ precautionary approaches and implement laws and regulations that protect environmental and human interests. While international systems exist and may be used to guide biosafety decisions, it is paramount for the country policy makers and regulators to be in charge of national decisions regarding modern biotechnology and this requires a well structured legal and regulatory system. In this era of globalization and also considering that country borders are in many cases porous, putting in place a biosafety regulatory system is an obvious necessity.

Major Objectives of a National Biosafety System

The major objectives of a national biosafety system are to:

1. Establish a science-based, holistic and integrated, efficient, transparent and participatory administrative and decision making system so that a country can benefit from modern biotechnology while avoiding or minimizing the possible environmental, health and socio-economic risks; and
2. Ensure that the research, development, handling, trans-boundary movement, transit, use, release, and management of GE products are undertaken in a manner that prevents or reduces risks to human and animal health, biological diversity and the environment.

Components of a National Biosafety System

A National Biosafety Framework is a system of legal, technical and administrative instruments set in place to address safety for the environment, humans and animals in the field of modern biotechnology

(Jaffe, 2005). The National Biosafety Framework (NBF) consists of the following key elements: national policies related to biosafety, regulatory regime, administrative and decision mechanisms, monitoring mechanisms, mechanisms for public awareness, education and participation, and scientific knowledge base, skills and capacity.

National Policies Related to Biosafety

The policy may be an explicit instrument or may be part of another relevant policy document such as the science and technology policy or the environment policy and provides for in-principal guidance on biosafety. The policy provides information for government stand on various aspects of biotechnology/ biosafety such as resource development, research and development, institutional framework, industrial applications, bioethics and public awareness. A national policy on biosafety has to be consistent with other policies on food and agriculture, environment and the overall country development objectives. The policy normally sets the basis for developing a strategy as well as legislation, implementing regulations and guidelines that eventually form the operational systems, for handling requests, risk assessment and risk management as well as for inspection, monitoring and enforcement (McLean et al 2002).

Regulatory Regime

The regulatory system for biosafety has to be supported by a legal instrument such as an explicit law of Parliament with its implementing regulations. In other cases regulations can be derived from a parent law such as that of Councils of Science and Technology (McLaen, 2002). Tanzania, for example, provides for Biotech in the NEMA law (Government of Tanzania, 2004). This means biosafety regulations can be developed based on this law. The objectives of the legal system are to: facilitate responsible research in modern biotechnology, to ensure an effective level of protection in the development, safe transfer, handling and use of genetically modified organisms; to establish a transparent and predictable process for reviewing and making decisions

on the transfer, handling and use of genetically modified organisms and related activities. The legal system will also establish administrative structures and spell out their functions and measures to be followed in their decision-making processes.

Administrative and Decision Mechanisms

Countries have used different approaches to establish administrative mechanisms/systems for biosafety. The Cartagena Protocol proposes the following model:

National Biosafety Focal Point: This provides contact with the outside world and this may be located in any appropriate government department. The focal point has a responsibility to provide coordinated communication on behalf of all relevant ministries, agencies, and departments of government on matters concerning the trans-boundary movement of LMOs with entities that produce, sell, import, export, transport or otherwise are engaged in the trans-boundary movement of LMOs, to governments, and international organizations, including the secretariat to the Biosafety Protocol.

Competent Authority: The competent authority carries out and coordinates the overall administration of biosafety in the country. This authority has responsibility to prescribe criteria, standards, guidelines and regulations for the management of biosafety. The competent authority has to establish a National Biosafety Committee (NBC) comprising a group of experts that can analyse applications dealing with GE and reach appropriate decisions based on scientific knowledge and national interests in relation to development, import, transit, contained use, release or placing on the market of a genetically modified organism. In addition to the NBC, the competent authority may assist institutions to establish Institutional Biosafety Committees

(IBCs) that will guide research activities dealing with GE activities. The competent authority has also to promote public awareness and provide for possible public participation in decision making. While some countries may establish one competent authority with membership from different relevant sectors, others may opt to have different competent authorities as per the sectors involved. African countries that are in the process of developing their biosafety systems, have proposed administrative structures that range from establishing semi-autonomous biosafety authorities or agencies to biosafety units within a government department.

Regulatory agencies: A range of government agencies such as Ministries responsible for the environment, agriculture, livestock, health, wildlife, fisheries, forestry, transport and communication, industry and trade, and science and technology may be designated with important responsibilities within the national biosafety system. The jobs range from issuing permits, inspections, monitoring and evaluation and other compliance procedures in relation to an established system.

Monitoring Mechanisms

The purpose of monitoring and evaluation is to track impact on biological diversity, the environment, and human and animal health. When referring to the environment, the main focus is on field trials and the commercial release of GE products. Thus, monitoring would determine the effects on the environment, which could be categorized as severe, moderate, low, negligible or no harm. In the case of plants, monitoring is undertaken to determine the level of horizontal gene transfer and effects on non-target organisms in order to develop a monitoring and evaluation prospectus. Monitoring of the GE products should be undertaken at different levels. Initial monitoring should be done at the project initiation phase to ensure that all things are organized according to the conditions

provided in the approval document. At later stages during the execution of the project, monitoring should be undertaken to ensure compliance. There are two different types of monitoring which can be associated with the release of GMOs: 1) Monitoring which is required by the government and is intended to confirm any assumptions made in the risk assessment procedures; and 2) Voluntary monitoring which is undertaken by the applicant in order to provide further information for his or her own purposes. The authorized party should comply to the reporting format set in the terms and conditions of authorization. However, for every GE product, when to undertake monitoring and when to evaluate the work needs to be determined. The same process would explicitly identify who would undertake the monitoring and evaluation, and who would receive the reports.

Mechanisms for Public Awareness, Education and Participation

While biotechnology, and in particular GE technology, is a complex technical subject, policy makers and other government officials have to make informed decisions for purposes of approval of products, rejection of application and for trans-boundary movements. The anticipated product end-users also need information to enable them to make informed choices. Most developed countries have low public awareness on biotechnology and biosafety, even amongst the scientific community. Therefore, it is crucial to involve a wide range of stakeholders through a consultative process in order to promote and facilitate public awareness and public participation as stipulated in Cartagena Protocol, which states that parties shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of GMOs. Parties shall further endeavor to ensure public awareness and education encompassing access to information on GMOs that may be imported, and should consult the public in the decision-making process regarding GMOs, and should make the results of such decisions available to the public. Hence biosafety communication is an integral part of biosafety procedures and is important for a number of reasons (Mugoya and Bananuka 2004):

a) For consensus-building on issues that affect people directly or indirectly;
b) To build a sense of ownership and collective responsibility;
c) To promote sustainable development;
d) To promote smooth implementation of the decisions;
e) To build transparency and accountability;

In many cases the biosafety regulations will compel the focal point or the competent authority to provide information to the public and provide for a public consultation mechanism. The Competent Authorities and other agencies, in making biosafety decisions, should promote and facilitate public awareness, education, and participation concerning the research, development, handling, trans-boundary movement, transport, use, transfer, release and management of GE products. They should incorporate into their respective administrative processes best practices and mechanisms on public awareness and participation. Public education and awareness should be promoted in terms of:

a) Imparting relevant information to stakeholders about specific issues;
b) Providing balanced information in terms of pros and cons;
c) Providing universal access to information;
d) Providing relevant information for informed participation;
e) Translating available information;
f) Reviewing curricula and improving training facilities; and
g) Providing short and long-term training on biotechnology and biosafety.

Public participation, on the other hand, should be promoted in terms of:

a) Involving stakeholders in decision-making and all processes;
b) Obtaining opinion from other people, passing on the information; and
c) Using a democratic process in reaching a common understanding and coming out with a common solution.

Procedures for public participation should include mechanisms that allow communication in writing or through public hearings, and which allow the submission of any comments, information, analyses or opinions.

Scientific Knowledge Base, Skills and Capacity

A strong knowledge base is a cross-cutting requirement at all stages of developing a national biosafety system. The level of expertise, knowledge and experience of the people directly involved in the design and operation of biosafety systems strongly influences the development and implementation of policies, laws, regulations, review and decision-making procedures. All concerned parties including the scientists, the concerned competent authority officials, the biosafety committees, the legal officials as well as the inspectors, must be conversant with the general principles of biotechnology and biosafety and have the necessary expertise to execute their role in the national biosafety system. The scientists have to consider biosafety issues from the concept stage as they decide what product to develop and what procedure to follow. The NBC must have the competence to conduct risk assessment based on the information in the application dossiers, though these may be supplemented with oral interviews.

Biosafety Risk Assessment

Risk has been defined as the combination of the magnitude of the consequences of the hazard if it occurs and the likelihood that the consequences will occur. Hence, risk assessment is inherently the most critical component of biosafety implementation. Any person developing a GE product must conduct a risk assessment and present the assessment report to the authority responsible for evaluation and approval of the product. The risk assessment will be based on possible harm to: human health, biodiversity, ecological processes and life support systems. Information for risk assessment is obtained from several sources. The applicant is the primary source through the risk assessment report, while the review teams can call on data from previous risk assessment reviews of the same GE product from other countries. The NBC has to

make sure that risk assessment is properly carried out and they may use in-house capacity or may outsource for additional information and scientific evidence. Hence, biosafety risk assessment is a paper exercise where NBCs review the content and analysis of the safety data presented. Some reviewers may wish to consider different concerns raised by different GE products and these may include socio-economic and ethical or cultural concerns. In case socioeconomic concerns are not evaluated as part of the review process, market forces will of course bring out the reality of the appropriateness of a particular GE product.

Characteristics of a Biosafety System

Jaffe (2005) has discussed important provisions that will help to make a national biosafety system operational. The system, should be understandable, workable, equitable, fair, adaptive, and enforceable (UNEP-GEF Biosafety Unit, 2004). Establishing such a system requires balancing different sector interests and properly defining roles and responsibilities. Key characteristics and components that are generally important to a functional and protective biosafety regulatory system are that it must be comprehensive, have adequate legal authority, conduct risk-based reviews, be transparent and understandable, be participatory, include post-approval monitoring, and be flexible and adaptable.

Comprehensive

A biosafety regulatory system should be all-inclusive (Jaffe, 2004). First, it needs to cover the different stages of development for a GE organism (UNEP-GEF Biosafety Unit, 2004), such as contained use, releases into the environment as confined field trial, unconfined field trials, releases for commercial production, and consumption of GE organisms as food or feed. According to von Grebmer (2005), a comprehensive regulatory system analyzes the range of potential safety issues associated with GE organisms including environmental and biodiversity, food safety issues and any other potential safety questions (such as worker safety). Finally, the regulatory system's scope includes all plants and animals that could be engineered and the different products

that may be produced. Comprehensive regulatory systems cover not just engineered plants used for food or feed but plants engineered to produce non-food substances, non-food crops such as trees, and engineered animals. However the scope of any country's regulatory system can be defined. For example, the scope of biosafety laws from several African countries covers the making, import, export, transit, contained use, release or placing on the market of any genetically modified organism or any product of genetically modified organisms. Such restrictions do not apply to genetically modified organisms that are pharmaceuticals intended for human use.

Adequate Legal Authority

The biosafety regulatory system should have a respected and sufficient legal authority to take a decision on a GE application and have its decision implemented. Each GE organism under review should be assessed in accordance with the intended use. For example, GE plants to be studied in containment or confined facilities may not need rigorous risk assessment for food-safety and environmental safety, whereas approval for unconfined release into the environment or for commercial production require complete risk assessment for safety factors (Jaffe, 2004; Cohen et al., 2005). Such legal authority over GE organisms helps ensure protection of the environment or human health. "Clear responsibility and legal authority is important not only for ensuring the protection of health and the environment, but also for providing the government, public and technology developers with a clear understanding of the regulatory pathway to market" (Pew Initiative, 2004). To ensure adequate legal authority for a biosafety regulatory system, countries need to decide whether they can establish a system using existing laws or whether they need to pass new biosafety-specific legislation. Whether a country passes a new law or uses existing laws, the legal authority for the biosafety regulatory system still needs to be exercised within that country's broader legal system, including its judicial system, and its other laws and regulations.

Well Articulated Safety Standards

Biosafety regulatory systems should establish safety standards for their approval processes to ensure consistency in the assessment process (Jaffe, 2004). The safety standard sets forth what level of protection must be satisfied to approve an application and what factors the NBC will consider before making an approval decision, including the baseline for any risk analysis. (UNEP-GEF Biosafety Unit, 2004). The standard also identifies whether the benefits from the GE organism or the opportunity costs of not introducing the organism will be considered. (Delmer, 2005). In a functional and protective system, all interested parties know and understand the safety standard beforehand and regulatory authorities' decisions have to apply to the safety standards in a uniform and fair manner for all applicants.

Proportionate Risk-Based Reviews

Biosafety regulatory systems look at each application individually and assess any potential risks to human health and the environment through a scientific risk-based analysis. The system should have flexibility to treat products differently based on the nature of the product and its use and hence in respect of potential risks and concerns raised (Delmer, 2005; Kinderlerer, 2002). It prioritizes applications it reviews based on the potential risk and gives the most scrutiny to products with the most relative risk while allocating less resources and time to products that raise less concern (Jaffe, 2005). For example, a confined field trial does not require the same detailed risk assessment as a commercial release of that same product. The confined trial is released under specific conditions, limited in duration, and designed to have minimal impact on the environment while the commercial release may not be controlled and will remain in the environment. Irrespective of the review procedure, all GE organisms must still meet the applicable safety standards. The procedures and the data needed to meet those standards, however, should vary depending on the nature of the product and its potential risks, so that the potential risks match the regulatory procedure. Thus, if a biosafety regulatory system allows for proportionate risk-based reviews, it seeks to minimize the regulatory costs for products with minimal risks.

Transparent and Understandable

An important component of a good biosafety regulatory system is transparency (UNEP-GEF Biosafety Unit, 2003, 2004). Public access to information about the regulatory system and the organisms that go through it can lead to greater public confidence in regulatory decisions (Pew Initiative, 2004). The information to avail should include: types of forms and procedures to be followed in submitting application, data requirements, time lines for the applicant, and standards and procedures to be followed in conducting the review. Mechanisms and means for the public to provide input and the treatment of confidential business information should also be availed. The information on a particular application, including the analysis followed and the reasoning behind the decision reached should be accessible (McLean et al., 2002).

A good regulatory system must also protect the confidential business information of applicants from disclosure. From a legal perspective confidential business is that information which is new, has economic value, and the economic value of which is enhanced by its being kept secret.

Participatory

Public participation is an important component in biosafety regulatory systems in democratic societies (UNEP-GEF Biosafety Unit, 2004; Mclean et al., 2002). Public participation can include the opportunity to provide information and comments to regulators on regulations, guidance documents, and specific applications before a regulatory decision has been made (Pew Initiative, 2004). It may also include the opportunity to provide oral and/or written testimony at public hearings. In most instances, the regulatory system responds to relevant comments in its decision-making documents to improve its overall decision and assure the public that any relevant concerns were seriously considered. Thus, while public participation helps to inform the decision-making process, the ultimate decisions remain with the regulatory agencies and the designated leaders.

Post-approval Monitoring

Assessment of a GE product for release does not stop at the approval for a specific use whether for confined field trial or for commercial use. The system continues to follow the performance of the released product in relation to human and environmental safety factors. Activities following approval can also include monitoring for compliance with any risk management conditions imposed on the GE organism (Cohen et al., 2005). A specific regulatory body should be identified and empowered to conduct post-approval monitoring following established operating procedures.

Flexible and Adaptable

Biotechnology is a rapidly changing discipline and it is impossible to fully anticipate the range of future applications. Thus, if a country is setting up a biosafety regulatory system to address currently unknown applications of genetic engineering, flexibility to adapt to new evidence on risks and benefits, and new types of products will be important. (von Grebmer, 2005; UNEP-GEF Biosafety Unit, 2003).

There are several ways to build flexibility and adaptability into a biosafety regulatory system. First, laws, regulations, and guidance can be written broadly to accommodate not just the products being proposed today but products that might be developed in later years. Non-flexible systems may fail to regulate new products or may have to put in place new laws, regulations, and procedures in place when confronted with new products. Second, the regulatory system should learn from its experiences regulating products and adapt accordingly. As the system regulates more products, it should become familiar with the benefits and risks of particular applications, allowing some applications with low risk to get a streamlined review process while increasing regulatory scrutiny for products that are similar to previous high-risk applications (Falck Zepeda and Cohen, 2005).

Status of National Biosafety System in Africa

While at least 40 African countries have ratified/accessed the Cartagena Protocol, most of them do not yet have functional biosafety systems. South Africa is probably the only African country with a fully functional system. Many other African countries are at various stages of establishing their biosafety systems and many of them have benefited from UNEP-GEf support for the purpose (see Table 2.1).

Table 2.1: Status of Biosafety Policy and Regulatory Frameworks in Select African Countries

Country	Cartagena Protocol	Biosafety framework (UNEP-GEF support)	Policy	Legal system
DR Congo	✓	✓		
Burkina Faso	✓			Draft
Egypt	✓			
Ethiopia	✓	✓		
Ghana	✓	✓	draft	Biosafety bill, various regulations
Kenya	✓	✓	✓	Biosafety bill, various regulations
Namibia	✓	✓	✓	Biosafety bill
Nigeria	✓	✓	draft	Biosafety guidelines
South Africa	✓		✓	GMO regulations 997
Tanzania	✓	✓		Incorporated in NEMA ACT
Uganda	✓	✓	✓	Biosafety bill, various regulations
Zimbabwe	✓	✓	✓	
Malawi	✓	✓	✓	Draft

Source: (SciDev Net 8th Feb 2008; personal communications) http://www.cbd.int/biosafety/

Challenges for the Development of National Biosafety Systems

There are a number of policy and regulatory challenges that slow down the development of biosafety systems in many countries of Africa. These include:

- Lack of clear priorities and investment strategies in science and technology in general and biotechnology in particular;

- Short-term and low-level financing of biotechnology and biosafety in research for development in many African countries;
- The role of intellectual property protection and its impact on the acquisition, development and diffusion of biotechnology;
- Institutions for administering industrial property rights particularly patents are still in their infancy;
- Inadequate product focus to drive the biotechnology industry with its associated biosafety needs.
- General lack of Understanding of biotechnology among policy makers and the general public and fears of the technology particularly when the general trend in Europe is still ranged from resistant to very cautious about the technology.

Opportunities for Regional Cooperation on Biosafety

While many African countries are in the process of developing their biosafety systems, a number of them have used existing legal provisions to initiate capacity building for the GE technology and the biosafety system. No substantial advancement, however, can be attained in this area until countries have government-approved policies and legal instruments.

As African agricultural regional bodies push for regional integration and creation of free trade areas, they are cognizant that regulating trade in products that contain or may contain GMOs and trans-boundary movement of GMOs across porous borders is a mega challenge. It is on these grounds that African leaders have demonstrated political will and commitment to cooperate and take a common approach to biotechnology and biosafety issues at regional levels. Developments in the direction of regional harmonization are conspicuous in the COMESA region, Economic Community of West African States (ECOWAS), Southern Africa Development Community (SADC) and the East African Community (EAC). The political goodwill at the regional levels presents opportunity for countries to learn together and support each other in establishing national biosafety systems.

REFERENCES

African Union. 2007. The African Model Law on Safety in Biotechnology. Available online at: http://www.nepadst.org/doclibrary/pdfs/amcost3_17_nov2007.pdf

CBD, Article 2. 1992. Available online at http//www.cbd.int/convention/articles

Clive James. 2007. ISAAA Brief no. 25. http://www.isaaa.org/resources/publications/briefs/35

Codex Alimentarius Commission. 2004. Joint FAO/WHO Food standards programme. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. www.codexalimentarius.net

Cohen, J., Komen, J., and Zambrano, P. 2005. "Public GM Innovations, Safety Regulation, and…Results?" Environment and Production Technology Division, IFPRI, Washington, D.C. Presentation at "The Globalization of Agricultural Biotechnology: Multi-disciplinary Views from the South", March 11-13, 2005 at the University of Warwick, Coventry, U.K.

Delmer, D. 2005. Agriculture in the Developing World: Connecting Innovations in Plant Research to Downstream Applications. Proceedings of the National Academy of Sciences, Vol. 103, No. 44, pp. 15739-46.

Falck Zepeda and Cohen. 2005.Biosafety Regulation of Genetically Modified Orphan Crops in Developing countries: a way forward. Pages 41-53 in The Economics *of Regulation of Agricultural Biotechnologies*. Eds: J. Alston, R.E. Just, and D. Zilberman. Proceedings of Orphan Crop Symposium. Center for Agricultural and Natural Resource Policy, University of Maryland, College Park, MD. Published by Springer, New York, NY.

FAO/ WHO. 1963. CODEX alimentarius, online available at: http://www.codexalimentarius.net/web/index_en.jsp

Goldstein, D.A., B. Tinland, L.A. Gilbertson, J.M. Staub, G.A. Bannon, R.E. Goodman, R.L. McCoy and A. Silvanovich. 2005. Human safety and genetically modified plants: a review of antibiotic

resistance markers and future transformation selection technologies. *Journal of Applied Microbiology* 99(1): 7-23.

Government of Tanzania. 2004. The Environmental Management Act. Online available at: http://www.lexadin.nl/wlg/legis/nofr/oeur/lxwetan.htm

Grant, E., Isaac, G. E. and W. A. Kerr. 2003. Genetically Modified Organisms and Trade Rules: Identifying Important Challenges for the WTO. *The World Economy* 26 (1), 29–42.

Guillemin, J. and M. Schoch-Spana. 2005. Bioterrorism: A response to Monica Schoch-Spana(AT 20[5]) *Anthropology Today* 21 (1): 23–24

Hill, R., Sam Johnston, Cyrie Sendashonga. 2004. Risk Assessment and Precaution in the Biosafety Protocol. Review of European Community & International Environmental Law 13 (3), 263–269.

Jaffe, G. 2004. Regulating transgenic crops: a comparative analysis of different regulatory processes. *Transgenic Research*, 13:5-19.

Jaffe, G. 2005. Comparative Analysis of the National Biosafety Regulatory Systems in East Africa: Fundamental Elements of a Functional National Biosafety System. IFPRI Discussion Paper, published by PBS East Africa.

McLean, M. A., Frederick, R.J., Traynor, P.L., Cohen, J.I., and Komen, J. 2002. A conceptual framework for implementing biosafety: linking policy, capacity and regulations. ISNAR Briefing Paper 47.

Pew Initiative on Food and Biotechnology. 2004. Issues in the regulation of genetically engineered plants and animals. Pew Initiative on Food and Biotechnology, Washington, D.C

SciDev Net 8th Feb 2008. Agri-biotech in sub-Sahara Africa: facts and figures. www.scidev.net

Schoch-Spana, M. 2004. Bioterrorism: US public health and a secular apocalypse. *Anthropology Today* 20 (5): 8–13

UNEP.2000. Cartegena Protocol on Biosafety to the Convention of Biological Diversity, Secretariat of the Convention on Biological Diversity, Montreal.

CBD. 1992. United Nations Convention on Biological Diversity (CBD) United Nations Treaty Series No. 1-30619. Signed during the 'Earth Summit' at Rio de Janeiro in June 1992.

United Nations Environment Programme-Global Environment Facility (UNEP-GEF) Biosafety Unit. 2003. Draft Guide for the implementation of national biosafety frameworks. UNEP-GEF Projects on Implementation of National Biosafety Frameworks, Geneva, Switzerland.

United Republic of Tanzania. 2004. The Environmental Management Act, 2004. Parliament of the United Republic of Tanzania, Dar es Salaam, Tanzania.

Von Grebmer, K. and Were Omamo, S. 2005. Lessons and Recommendations: Biotechnology, Agriculture, and Food Security in Southern Africa. IFPRI and FANRPAN, Washington, D.C. and Harare, Zimbabwe.

3

Biosafety and Biotechnology in Uganda

OVERVIEW

The biosafety regulatory system in Uganda is overseen by the Uganda National Council for Science and Technology (UNCST). The National Biosafety Committee (NBC) was established by UNCST to address the country's immediate biosafety needs including drafting of the necessary laws, regulations and guidelines. Uganda ratified a number of conventions including the Convention on Biological Diversity (CBD) in1993 and the Cartagena Protocol in 2001. An examination of a national biosafety system taking into account its adequacy to legal authority, safety standards, transparency, public participation, flexibility and adaptability of the system, among others, is vital. The national biosafety system has been shaped by the Cartagena Protocol, World Trade Organization agreements such as the Sanitary and Phystosanitary Measures (SPS) Agreement, the General Agreement on Tariffs and Trade and the Technical Barriers to Trade Agreements, The Codex Alimentarius Commission, and the International Plant Protection Convention. The national biosafety system should be continuously reviewed to ensure it is comprehensive, understandable, workable, and fair, given that the country is getting more involved in the development of genetically modified organisms (GMOs).

ROLE OF NATIONAL BIOSAFETY COMMITTEES IN BIOTECHNOLOGY DEVELOPMENT

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Introduction and History to the Uganda National Biosafety Committee

The Uganda National Biosafety Committee (NBC) which started in 1996, has its strong origins on the protection of biological agents, the safety of the people working and using biological agents and materials in diagnostic and research laboratories, hospitals, industry and now biosafety includes the application of modern biotechnology, such as recombinant Deoxyribonucleic Acid (rDNA) and Ribonucleic Acid (rRNA) in the protection of biodiversity, enhanced food security, improved health and biosecurity of nations following the introduction of Genetically Modified Organisms (GMOs).

NBC is also the Regulatory Committee of the competent authority, the National Council for Science and Technology (UNCST) in Uganda. It ensures the meeting of standards for transfer, handling and use of, including disposal of, such biological materials.

Biosafety is a concept of the need to protect human health and the environment from possible adverse effects of modern biotechnology (CBD, 2000). Modern Biotechnology at the same time is recognized as having the potential for the promotion of human well-being, particularly in meeting critical needs for food production, agriculture in general and human health (CBD, 2000). The National Focal Point of the Cartagena Protocol is the Ministry holding the portfolio of Environment in the Government of Uganda and it coordinates biosafety matters with regard to biodiversity preservation under the Cartagena Protocol. Biosafety also refers to the prevention of large-scale loss of biological integrity, focusing on protecting the agent, human health and the environment. Components of biosafety include ecology involving imported life beyond

ecological borders; agriculture, reducing the risk of food contamination from alien genes; health, arising from unacceptable gene flow to humans; chemistry, toxic levels in the food chain and human health; and biomedical laboratories as far as contamination of the test material, animals and/or humans working in laboratories; and Exobiology, managing a possibility of any life from out-of- space mixed with that on earth (CBD, 2000). It requires the application of the Precautionary Principle of the Cartagena Protocol (Prevention is better than cure: Look before you leap: Better safe than sorry).

Since the inception of NBC in 1996, UNCST has instituted not only the NBC but also the Institutional Biosafety Committees (IBCs), the most active of which is the National Agricultural Research Organization (NARO) (UNCST, 1996). The Biotechnology and Biosafety policy has been submitted for approval by Government authorities and is due for approval by the cabinet of the Government of Uganda (UNCST, 2007). Several components of the Biotechnology and Biosafety frameworks (Protocol Manuals and Standard Operating Procedures-SOPs) have been put in place, particularly in the crop sector (Manual for Confined Field Trials, 2006). This has culminated into the approval of the confined transgenic banana and soon, for cotton and cassava research. Research in transgenic fish, trees, pharmaplants, animals and disease-causing agents is not yet being conducted in Uganda. However, laboratory-based biotechnology research and application does occur within the national research systems involving Universities and Research Institutes of Uganda (both public and private).

There is need to activate Institutional Biosafety Committees (IBCs) in Uganda, especially in Universities, and other ethical research committees, especially those involved in the use of animals in research, to compliment the ethical committees on research involving humans operating at Makerere, Mbarara and Gulu Universities Medical Schools on behalf of UNCST. According to supply and demand principles of economics, biotechnology development will depend on the supply and demand of biotechnology as enabled by the governments of a particular country and their respective NBCs.

Appointment and Composition of the NBC

National Biosafety Committee members are appointed by the Minister on recommendation of the competent authority and are selected based on key areas of competence, also taking into consideration representation of key stakeholder groups and agencies as specified in the Second Schedule (UNCST, 2007). A member of the NBC shall hold office for a period not exceeding five years from the date of appointment and shall be eligible for reappointment only once upon expiration of the term; may resign his/her office upon giving one-month notice in writing to the Minister; may be removed from office if they have been absent from 3 consecutive meetings of the committee without the permission of the Chairperson; or if in the opinion of the Minister, they are unable to discharge the functions of the office due to infirmity of the body or mind or for misconduct, or misbehaviour; and where a member of the NBC has resigned or been removed from office, the Minister shall in consultation with the competent authority make a new appointment.

Composition of the NBC

Membership comprises of the following:-

1. A representative of Agricultural Policy and Inspectorate (Ministry of Agriculture Animal Industry and Fisheries)
2. A representative of Agricultural Research (National Agricultural Research Organization, NARO)
3. A representative of the Ministry with the portfolio of Environment and responsible for the Focal Point according to the Cartagena Protocol
4. A representative of the National Environmental Management Organization (NEMA)
5. A representative of Ministry with the portfolio of Health
6. A representative of Ministry with the portfolio of Trade and Industry

7. A representative of Uganda National Bureau Standards (UNBS)
8. A representative of Consumer Protection
9. A representative of Farmers
10. A representative of Legal Sector
11. A representative of Regional Biosafety specialist
12. A representative of Universities
13. A specialist in Crop Agriculture
14. A specialist in Social Sciences.
15. A specialist in Veterinary Medicine

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety (CPB) and the Conservation of Biological Biodiversity (CBD) both of the United Nations (UN) (CBD, 2000), are responsible for the interrelated Biosafety and Environment Biodiversity. The Precautionary Principle (Freestone and Hey, 1996), of "Look before you leap" or "Prevention is better than cure" and/or "Better safe than sorry" applies to moral or political acts which may cause harm to the general public and must be exercised with the burden of proof using scientific consensus, so as to cause a minimal level of harm. The human act in the case of biosafety applies mainly to biological systems which are not easily contained unlike physical systems. Biosafety includes all actions by humans that involve the handling of biological agents in biomedical laboratories, agriculture, medical and veterinary application, their impact on the environment and its associated biodiversity. In this context, the NBC has according to Hellman et al., (1973), appreciated the role of the following in making its decisions on genetically modified organisms and biosafety:-

A. The impact of human actions in benefiting Uganda crop Agriculture;
B. Ethical responsibility due to the act;
C. Having applied a range of interpretations**.**

A. The impact of human actions in benefiting Uganda crop Agriculture and protecting humanity on the following are appreciated:

- Environment through deforestation, depopulation of biodiversity, extinction of species, threatening existing biodiversity and/or overpopulation of the same species (weed development & Monoculture);
- Threats or benefits to human livelihoods;
- Threats or benefits to food security;
- Threats or benefits to health;
- Threats or benefits in Laboratory security;
- Threats or benefits to National security.

The impact of human actions to protect humanity requires a willingness to take action through the NBC in advance of scientific proof or as evidence of the need for the proposed action (do something about it even with insufficient knowledge) on the grounds that further delay will prove ultimately costly to society and nature, and in the long term it is selfish and unfair to future generations if action is not taken with caution.

B. Ethical responsibility due to the act;

Ethical responsibility due to the human act by cross-checking the Biosafety protocols for efficacy and efficiency is important to NBC. This is done by maintaining the integrity of natural systems, recognising fallibility of the human understanding, and ensuring that the technology is without major harm before being approved, adopted or used.

C. Having applied a range of interpretations;

The following ranges of interpretations are important while making decisions at the NBC in order to protect humanity:

- Risk of exposure to biohazards (bacteria, rickettsia, viruses, prions, chemical carcinogens and recombinant DNA) is both ancient and recent;
- Cost-benefit analysis;
- Opportunity cost of not acting;
- Option value (wait before you act); and
- Politics of power and money control regarding Biosafety issues.
- This further supports the decision-making process of protecting the Scientist and the Consumer, through strict application of the precautionary principle, by inaction, when action poses a risk.
- The other action could be if active application of biotechnology leads to harm affecting the status of innovation and therefore all innovations must be subject to risk assessment in order to prevent the risk.
- Precautionary principle by choosing the less risky alternative (risk assessment); and taking responsibility for the potential risk (weighing legal implications).

Risk assessment is associated with a cause-and-effect relationship, espousing a dose-effect response to humanity and environment; the threshold of plausibility (does it make scientific sense); time-frame linkage (before, it was not; but after, it is); the association and evidence of harm already established elsewhere; capacity building to train human resource; establishment of suitable research facilities (laboratories, hospitals and green houses); establishment of Protocols for Standard Operating Procedures in Practice, Inspection and Granting operations (Regulation); and communication and public awareness.

The epidemiological chain of events must be noted when assessing exposure. These include: agent, source, mode of transmission, and entry to the host, depending on the level of the biological hazard or biological level safety (BLS), to include, according to the Centers for Disease Control (CDC, Atlanta, GA, USA), these 4 groups of agents are:

BSL-1: Well-characterized agents not known to consistently cause disease in healthy adult humans and are of minimal potential hazard to laboratory personnel and the environment.

BSL-2: Agents of moderate potential hazard to personnel and the environment.

BSL-3: Indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. [Note that there are typically medical prophylaxis (vaccines) or treatments for these agents.]

BSL-4: Agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. [Note that the majority of agents in this category are viruses and there are typically few medical countermeasures for the disease caused by these agents.]

The containment control of bio-hazardous agents includes: recognition of agents that contain or exclude (or both) highly carcinogenic chemicals; for example, Ethidium bromide used in DNA research, evaluation to include risk Assessment depending on the possibility of grave danger and Prescription which includes:

a) Primary barriers – for individual workers i.e. Safety cabinets;
b) Secondary barriers - Building features to prevent escape into the community;
c) Personnel practices, hygiene, prohibiting eating of food in laboratories;
d) Decontamination in the event of spillage.

Testing and surveillance is important to establish if the measures put in place are effective which would lead to an employee health programme to include vaccination and serological analysis.

Analysis and Certification includes insurance that all precautions have worked, that is no cases after a given period. Analysis and certification also includes educational Programmes for groups at risk, and biosafety Policy implementation through accident reporting, handling of clinical issues, bites, scratches, needle pricks, accidental exposures, wounds and warning of possible infections acquired at work, for example rabies, salmonella, laboratory-acquired infections and radiologic safety. Analysis and certification should also look at personnel practices and operational procedures which include protective clothing worn in laboratories, gloves worn during any risky procedures, protective clothing washed weekly (autoclaved), safety shoes and clothing worn when working with animals, complete clothing change when working with animals, no eating, drinking, smoking permitted, mouth pipetting prohibited, hands washed after procedures and before departing, no children permitted in the labs, only authorized personnel allowed in operational and storage areas, warning signs posted to all access areas, safety regulations posted, safety action plans completed, storage containers of hazardous materials labelled, inventory of hazardous material maintained, stored hazardous material secure, minimal quantities of hazardous material allowed, transport in non-breakable impervious containers, decontamination of materials done before washing, spilled chemicals/carcinogens decontamination before, impervious work surfaces, no aerosols at work, floors kept clean, corridors free of equipment and animals, and laboratory safety survey done regularly, among others.

Biotechnology Development Promoted by NBCs

This is further driven by the economic laws of supply and demand as explained here under:-

Supply side, economic requirements, and their availability in the country

Biotechnology development depends on the following items related to supply:

1. Personnel (Academicians and Innovators actively involved in development and providing an enabling environment for other innovators);
2. Laboratory infrastructure and information (Universities, Research Centres, Regulatory Centres and Industry);
3. Funding (National and International);
4. Industry - University-Research Centres linkage for product development; and
5. National policies (Research and Development legal framework, Intellectual Property Rights (IPR), Small venture capital, Commercialization and Regulations).

Demand side, economic requirements, and their implementation by the country

Biotechnology development depends on the following items related to demand:

1. Market Size (Depends on Public acceptance and share in ownership of technology/trade agreements);
2. National procurement policies for biotechnological products (Food, Drugs and Technology), enhancing local markets for own products;
3. Public Perceptions of Biotechnology (Fear as opposed to Acceptance); and
4. Biosafety Regulations (should be facilitating instead of obstructing).

REFERENCES

CBD. 2000. Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Secretariat of CBD, Montreal, Quebec, H2Y, 1N9, Canada.

Freestone D. and Hey E. 1996. Origins and development of the Precautionary Principle. In the Precautionary Principle and the Law. Kluwer Law International, Netherlands. pp.3 – 15.

Hellman, A., Oxman, M. N., and Pollack, R. 1973. Biohazards in Biological Research. Proceedings of a Conference held at Asimolar

Conference Centre. Pacific Grove, CA. January 22-24, 1973
Manual for Confined Field Trials. 2006. Manual for confined field trials of genetically modified plants. UNCST, Government of Uganda, Kampala, Uganda.
UNCST. 1996. The National Biosafety Committee of the National Council for Science and Technology. Ministry of Finance, Planning and Economic Development, Government of Uganda, Kampala, Uganda.
UNCST. 2007. The Biotechnology and Biosafety Draft Policy. Uganda.

ANALYSIS OF UGANDA'S BIOSAFETY REGULATORY SYSTEM

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Uganda is a landlocked East African country bordered by Kenya, Sudan, Rwanda, Tanzania and the Democratic Republic of the Congo (DRC). Covering a land area of 241,000 square kilometres, the country comprises varied ecosystems including grassland savannah, rainforest and lakeshores. The climate is tropical. The country is classified among the least developed countries. In 1999, 85per cent of the population (approximately 25 million) lived on less than one US dollar per day. Currently, 38% of the population lives below the national poverty line and life expectancy is low, at 50.74 years for males and 52.46 years for females. The country was ravaged by the HIV pandemic, and the HIV / AIDS infection rates that currently stand at 4.1 per cent of the adult population remains an important challenge; although this figure has dropped from a 15per cent infection rate in the 1990s. The infant mortality rate is also high, at 67.83 deaths per 1000 births. Approximately 40per cent of the population is illiterate, though this is considerably lower in the 15-25 year age group. The country is a predominantly Christian (66%), but is also home to a significant number of Muslims

(15%) and those with animist beliefs (18%), mainly associated with various tribal identities. Agriculture is very important in Uganda, both for its contribution to export earnings and domestic trade, as well as for its integral role in the subsistence lifestyles of a significant proportion of the population. It accounts for 44% of gross domestic product (GDP) and the activities of 82% of the workforce. Key crops include maize, bananas, cassava, potatoes, rice, sorghum, sugarcane, coffee, tea, tobacco and cotton; of these, coffee is the primary export earner. (Johnston et.al., 2008)

In 2000, the government launched a Plan for the Modernization of Agriculture (PMA) which provides a framework for eradicating poverty through multi sectoral interventions aimed at improving the welfare of poor subsistence farmers. The PMA document recognizes the contribution of agriculture to the national economy and calls for the establishment of strategic research to include genetic resources conservation and biotechnology to ensure the country's capacity to cope with the global scientific trends so as to be able to take advantage of the technological advances for the benefit of farmers.

Current Status of Biosafety in Uganda

The government of Uganda has designated the Uganda National Council for Science and Technology (UNCST) as a competent authority to oversee functions of biosafety in Uganda. As an interim measure, the UNCST established the National Biosafety Committee (NBC) to be responsible for addressing any immediate biosafety needs and especially the drafting of the necessary laws, regulations, guidelines, and other documents necessary for the functioning of the biosafety regulatory system. The committee is made up of representatives from government agencies and civil society (Nyiira et al. 2000). It was responsible for drafting Guidelines on Biosafety in Biotechnology for Uganda, the National Biotechnology and Biosafety Policy, the Biosafety Bill, and a number of manuals and SOP addressing specific issues surrounding biosafety regulation, such as containment and confinement. NBC has

reviewed several applications for GMOs, some of which are currently undergoing confined field trials. However, an important issue has arisen with these interim measures and some doubts have been raised as to whether there is any legal authority to support them. A number of government organs are actively involved in the governance of biosafety and biotechnology in Uganda (see Box 3.1).

Box 3.1
Government Organs and NGOs Involved in the Governance of Biosafety and Biotechnology in Uganda

- Ministry of Finance, Planning and Economic Development
- Ministry of Water, Lands and Environment
- Ministry of Agriculture, Animal Industry and Fisheries
- Ministry of Health
- Ministry of Trade and Industry
- Ministry of Justice and Constitutional Affairs
- National Agricultural Research Organization (NARO)
- National Environment Management Authority
- National Planning Authority
- Uganda National Council for Science and Technology (UNCST)
- Uganda National Bureau of Standards
- Uganda Revenue Authority
- Uganda Wildlife Authority.
- Makerere University
- Uganda National Academy of Sciences
- Uganda Consumer Protection Association (UCPA)
- Advocates Coalition for Development and Environment (ACODE)
- Consumer Education Trust of Uganda (CONSENT)

Against the above background, Uganda ratified the Convention on Biological Diversity in 1993 and the Cartagena Protocol in 2001. This

commitment spurred the country to embrace a range of regional and international capacity building initiatives. A number of major capacity building efforts relating to Biotechnology and Biosafety in Uganda have been developed (see Box 3.2).

Box 3.2 Timeline in the Development of the Biosafety Regulatory System in Uganda

1993	Uganda ratifies Convention on Biological Diversity.
1996	Uganda establishes a National Biosafety Committee (NBC)
1997	Uganda participates in UNEP-GEF Pilot Biosafety Enabling Activity Project.
1998	Uganda embarks on Drafting of Biosafety Regulations.
1999	The BIO-EARN Project established in Uganda
2000	Uganda launches the Plan for Modernization of Agriculture (PMA) which recognizes role of Biotechnology
2000	Uganda signs Cartagena Protocol on Biosafety.
2000	Uganda's NBC reviews 1st GMO application
2001	Uganda ratifies the Cartagena Protocol on Biosafety
2002	Uganda participates in UNEP-GEF Project on the Implementation of the National Biosafety Framework.
2002	USAID ABSP II Project established in Uganda.
2003	Government develops a national position on Biotechnology
2004	Programme for Biosafety Systems (PBS) initiated.
2004	Uganda's Biosafety and Biotechnology Policy is submitted to Ministry of Finance Economic Planning
2007	The first Confied Field Trial of genetically modified plants for experimentation planted by NARO at Kawanda
2008	Consideration and adoption of the National Biotechnology and Biosafety Policy by Cabinet

Examination of Uganda's Biosafety Regulatory System

A biosafety regulatory system is judged on the basis of the extent to which it is comprehensive, legally authoritative, responsive, transparent, participatory, efficient and workable (Jaffe, 2004).

Scope of Uganda's Biosafety Regulatory System

A biosafety regulatory system is comprehensive in scope when it covers the different stages of development of the GMO such as releases into the environment, confined field trials, releases of commercial products, and consumption as food. Second, it has to analyze the range of potential safety issues associated with GMOs, including the environmental and biodiversity issues highlighted in the Biosafety Protocol, but also food safety issues and any other potential safety questions (such as worker safety).

The interim biosafety regulatory system defines biosafety to cover the "transboundary movement, transit, handling, and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and defines living modified organisms (LMOs) as organisms that contain novel genetic material introduced through *in vitro* techniques (e.g. recombinant DNA) or cell fusion (Article 3). The scope embraces two particular uses of LMOs: (1) those that will be intentionally introduced into the environment; and (2) those directly used for food, feed, or processing (FFP).

The interim biosafety system makes very general statements on the key components of the scope. It covers contained use, introduction into the environment, and the placing of GMOs on the market. The Uganda draft National Biotechnology and Biosafety Policy defines biosafety to include risks posed to human health and states that potential risks to human health are to be addressed through a comprehensive biosafety regulatory system. However, it lacks certain key details, including the following elements:

(a) It does not provide a detailed discussion about which agency will be responsible for ensuring the food safety of GMOs;
(b) It does not state the procedures to be used in conducting any food safety assessment, nor the legal authority under which that agency would take action. This is in sharp contrast to the extensive discussion about how each system addresses environmental risks;
(c) The system does not distinguish GMOs based on the products they produce, so it tends to treat and bunch GMOs for food, feed, industrial purposes, and pharmaceuticals together as one; and
(d) It does not clearly address food safety regulatory processes for GMOs as a component of the biosafety regulatory system as distinct from environmental issues.

To ensure that a biosafety regulatory system is in place that can address the full range of potential risks that arise from GMOs , Uganda needs to identify how food safety issues will be addressed. One way of doing this is to designate and indicate in the biosafety policy some existing food laws and agencies that would address food safety concerns for GMOs and summarize the procedures that will be used for any review and approval process.

Adequacy of Legal Authority

Clear responsibility and legal authority is important not only for ensuring the protection of health and the environment, but also for providing the public and technology developers with a clear understanding of the regulatory pathway to market (Pew Initiative, 2004). The biosafety regulatory system needs sufficient legal authority to subject each GMO to a food-safety and environmental risk assessment and approval process before any unconfined release into the environment or before any GMO is placed into commerce (Jaffe, 2004; Cohen et al., 2005). Uganda has moved in the right direction to draft new biosafety-specific legislation. The new laws will empower the authority to: protect the environment; issue permits and conduct inspections; conduct risk assessments;

approve activities; permit activities, or conduct inspections—powers safeguarding the environment or human health from science and related technology activities.

Adequacy of the Safety Standard

A key component of a biosafety regulatory system is to have a clearly articulated safety standard which sets forth what level of protection must be satisfied to approve an application and what factors the government will consider including details on socio-economic considerations to be used to judge applications for approval by the government as baseline for any risk analysis review (UNEP-GEF Biosafety Unit, 2004). Without such sufficient details, the system could be perceived as unfair to the applicants and the public who need to know how specific applications will be judged. Moreover, lack of such details violates both the Biosafety Protocol or WTO obligations.

The interim Ugandan biosafety regulatory system does not provide details of such standards. While the policy recognizes the need to address socio-economic considerations that might arise from individual GMOs, it does not elaborate on what socio-economic considerations will be considered, how they will be analyzed, and how they will be factored into the decision-making process. In finalizing the Uganda Draft Biosafety Bill effort should be made to provide the legal standard or safety standard that must be met for an approval to be made in addition to mandatory information submitted by the applicant, the risk assessment, the relevant comments from the public, among other requirements.

Upholding the "Case to Case" Analysis Principle

Biosafety regulatory systems should be able to review applications on a case-to-case basis assessing any potential risks to human health and the environment through a scientific risk-based analysis (Jaffe, 2005). For example, a confined field trial does not require the same detailed risk assessment and governmental review as a commercial release of

that same product. The confined trial is released under specific conditions, limited in duration, and designed to have minimal impact on the environment, while the commercial release may not be controlled and will remain in the environment. This differentiation allows the regulator to streamline the approval of safer applications while spending more time and resources on applications that pose greater relative risk (Kinderlerer, 2002); and in so doing, minimizes the regulatory costs for products with minimal risks.

The interim biosafety regime recognizes that different activities with a GMO have different relative risks. The details are not clearly articulated. Thus, in finalizing the biosafety bill, effort should be made to clearly distinguish applications for contained use, confined field trials, and commercial release, and not to treat them in same way (i.e. requiring the same procedures, data and risk assessment).

Adequacy of Transparency

Public access to information about the regulatory system and the organisms that go through it can lead to greater public confidence in regulatory decisions (Pew Initiative, 2004). Biosafety regulatory systems that are transparent and understandable usually provide to the public information about:

- The regulatory process, including the steps, data requirements, and time lines for the applicant (a roadmap of the process and what is expected of the applicant);
- Who is accountable, where, when and how the public can be involved in the regulatory process; and
- The agency decision on a particular application, including the analysis of a particular application and the reasoning behind its decision (McLean, et al., 2002).

The Uganda Biosafety Bill has provisions that are consistent with the Biosafety Protocol, which promotes transparency but allows for protection of confidential information. Attempts have been made to put

in place structures and mechanisms showing how the regulatory system will process applications, what information the public will have access to, what opportunities for public participation exist in the process, and what is the basis for any decisions. In addition, the system has attempted to protect from disclosure confidential business information of applicants. Thus, in finalizing the Bill, effort should be made to have provisions that balance the rights of the public to information with the rights of the developer or applicant to protect confidential business information.

Adequacy of Public Participation

Public participation in a biosafety regulatory system usually involves two separate components: (1) the opportunity to provide comments and opinions on the laws, regulations, and policies before they are adopted, and (2) the opportunity to provide comments before an application for a GMO is approved by the regulatory agency. Thus, while public participation helps to inform the decision-making process, the ultimate decisions remain with the regulatory agencies and the designated leaders.

Uganda's biosafety system has involved the public in the process of drafting their biosafety regulatory system (laws and regulations) and their biosafety policy. Uganda has conducted a number of public stakeholders meetings beginning in 2001 to address the country's biosafety policy and biosafety law (CONSENT, 2003). Uganda has also provided for some level of public participation in the review and approval process for individual GMOs. Thus, whereas Uganda has provided the opportunity for the public to comment on applications, the value of that opportunity depends on how those comments are used in the decision-making process.

Flexibility and Adaptability of the System

Biotechnology is a rapidly changing discipline and it is impossible to fully anticipate the range of future applications. Therefore, flexibility to adapt to new evidence on risks and benefits and new types of products is important. While Uganda has evaluated a number of GMO

applications, it has not had ample opportunities to test the flexibility and adaptability of its system.

Therefore, as Uganda develops its biosafety bill, it will be important to incorporate flexibility and adaptability into the biosafety regulatory system. Laws, regulations and guidelines should be written broadly to accommodate not just the products being proposed today but products that might be developed ten or twenty years from now. The regulatory system should learn from its experiences in regulating products and adapt accordingly.

As Uganda's system regulates more products, it should become familiar with the benefits and risks of particular applications, allowing some applications with low risk to get a streamlined review process while increasing regulatory scrutiny for products that are similar to previous high-risk applications (Falck Zepeda and Cohen, 2005).

The Major International Obligations that have Shaped Uganda's Biosafety Regulatory System

Uganda has not enjoyed complete discretion in deciding how it sets up its biosafety regulatory system. A number of major international agreements, treaties and obligations relating to biosafety to which Uganda is signatory and must be compliant have been taken into account while establishing the system. These include the Cartagena Protocol, the World Trade Organization agreements, the Codex alimentarius and the International Plant Protection Convention.

Cartagena Biosafety Protocol

The Cartagena Biosafety Protocol which became effective on September 11, 2003, is a binding international agreement under the Convention on Biological Diversity signed in 1992. The Protocol establishes procedures and legal obligations to assess and manage the potential risks of Living Modified Organisms on biological diversity, taking also into account risks to human health.

The Protocol's scope is the "transboundary movement, transit, handling, and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4); and defines LMOs as organisms that contain novel genetic material introduced through *in vitro* techniques (e.g. recombinant DNA) or cell fusion (Article 3).

The Protocol addresses two particular uses of LMOs: (1) those that will be intentionally introduced into the environment; and (2) those directly used for food, feed, or processing (FFP). The Protocol:

- Sets up two separate procedures to ensure the safe transfer, handling and use of LMOs. (a) It sets up an "Advance Informed Agreement (AIA)" procedure (Articles 7, 8, 10, 15, 16) (b) It sets up a procedure for those LMOs, where the AIA procedure is not required (Article 11);
- Establishes a system which gives proportionate treatment to an LMO based on its proposed use;
- Provides differentiated treatment of LMOs based on particular risk characteristics and allows parties to undertake activities under containment in a laboratory or greenhouse and leaves their regulation to the discretion of the individual country (Article 7);
- Sets up a "simplified procedure" that allows certain LMOs that would normally qualify for the AIA procedures to have a streamlined process or complete exemption from AIA if that LMO can be released safely (Article 13);
- Provides details about the information needed for a risk assessment (Annex II) and an explanation of what a scientific risk assessment of an LMO should entail (Annex III); and
- Does not cover products derived from LMOs, such as processed foods that have ingredients that came from LMOs.

Although the Protocol comprehensively covers many issues, it leaves unresolved issues that each country must address when establishing their biosafety regulatory regime because:

- There is no discussion about what level of protection is adequate before an LMO is approved or how much potential risk must be identified to justify withholding consent;
- It is silent on what happens after a risk assessment has been conducted and some potential risks are identified (as will invariably happen since most activity has some potential risk);
- It does not adequately define what socio-economic considerations include and does not explain how they might be factored into the procedures set forth in the Protocol;
- It does not comprehensively address all the major risk issues associated with GMOs; and
- It does not substantively address human health or food-safety concerns surrounding LMOs.

The Protocol therefore has been the primary driving force behind the establishment of Uganda's national biosafety regulatory system. It is empowering Uganda to establish biosafety procedures through the provision of scientific and legal boundaries under which the systems should operate to create a uniform, comprehensive biosafety regulatory process.

World Trade Organization Agreements

A number of World Trade Organization (WTO) agreements have had a direct impact on biosafety regulatory systems. These include: Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the General Agreement on Tariffs and Trade (GATT), and the Technical Barriers to Trade Agreement (TBT).

Sanitary and Phytosanitary Measures (SPS Agreement)

This agreement provides countries with the sovereign right to establish appropriate levels of sanitary and phytosanitary protection in international trade, which includes the areas of food and agriculture. Under the SPS Agreement, those protections must do so in a way that minimizes negative trade effects. The SPS Agreement also requires that countries "avoid

arbitrary or unjustifiable distinctions in the level of protection they consider to be appropriate for different situations, if such distinctions result in discrimination or disguised restrictions on international trade" (Zarrilli, 2005). The SPS Agreement does allow countries to adopt precautionary measures when relevant scientific evidence is insufficient (similar to Protocol) but only allows that decision to remain for a reasonable period of time while additional scientific evidence is actively gathered (Kinderlerer and Adcock, 2005). Finally, the SPS Agreement also sets forth risk assessment procedures that include the use of both scientific and socio-economic considerations (SPS Agreement), but it provides a fairly narrow definition of which socio-economic considerations can be legitimately used in the decision-making process. Thus, the SPS Agreement may restrict the scope of a biosafety regulatory system.

General Agreement on Tariffs and Trade (GATT)

This agreement requires that "like products" be treated in the same manner, whether produced domestically or imported. Under GATT, it is unclear whether GE products can legitimately be distinguished solely by their process of production (Zarrilli, 2005).

The Technical Barriers to Trade Agreement (TBT)

This agreement requires that countries' technical regulations may not be more trade-restrictive than necessary to fulfil a legitimate objective (The World Trade Organization, 1995b). The TBT may be relevant to provisions on the labelling and tracing of GMOs and their products, where various regimes may not meet the "no more trade-restrictive than necessary" requirement.

The SPS and TBT Agreements encourage the use of international scientific standards. The SPS Agreement recognizes the standards developed by three relevant organizations: the FAO/WHO Codex Alimentarius Commission, the Office of International des Epizooties (OIE – the World Organization for Animal Health), and the International Plant Protection Convention (IPPC). All those standard-setting bodies

have their working groups on safety aspects of GMOs and GM foods, and the resulting standards, recommendations, and guidelines may become the basis for WTO members' sanitary and phytosanitary measures or technical regulations.

The Codex Alimentarius Commission

The Codex Alimentarius Commission was established under the auspices of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop internationally acceptable standards for use in the areas of food quality and food safety. The SPS Agreement specifically cites Codex standards, guidelines, and recommendations as the preferred international measure for facilitating international trade in food. The Codex has been working on food safety issues surrounding GMOs and their food products for a number of years and has generated consensus documents that discuss how to conduct food safety risk assessments for GMOs and their food products. Those documents include 'Principles for the Risk Analysis of Foods Derived from Modern Biotechnology' and 'Guideline for the Conduct of Food Safety Assessment of Food Produced Using Recombinant-DNA Microorganisms'. It is important that Uganda internalizes these documents as it elaborates on its biosafety regulatory system, especially while taking biosafety decisions involving food safety issues.

International Plant Protection Convention

The International Plant Protection Convention (IPPC) establishes the sovereign authority to regulate the entry of plants, plant products, and other regulated articles with the use of phytosanitary measures. Those measures, however, must be technically justified, transparent, and not applied in a way that constitutes either a means of arbitrary or unjustified discrimination or a disguised trade barrier. The IPPC currently has working groups addressing issues involving GMOs that fall within the scope of the international agreement and it is important that Uganda internalizes the progress as it elaborates on its biosafety regulatory system.

Conclusion

The construction of Uganda's biosafety system is still an ongoing process. Some of the major conclusions and recommendations from this analysis are as follows:

1. The Ugandan biosafety system has not yet addressed all issues in a comprehensive manner and some loopholes may arise in its adequacy to protect the environment, in issuing permits, conducting inspections, conducting risk assessments, approving activities, permitting activities, or conducting inspections and safeguarding human health.
2. Food safety is a necessary component of the biosafety regulatory system. Uganda needs to identify how food safety issues will be addressed.
3. Uganda's biosafety regime should adequately recognize that different activities with a GMO have different relative risks. The system should therefore distinguish applications for contained use, confined field trials, and commercial release and not to treat them in same way - that is, requiring the same procedures, data and risk assessment.
4. Uganda's biosafety system should clearly state the nature of socio-economic considerations to be included in the assessment process for GMOs and these should be limited to impacts that are closely linked to biodiversity.
5. Uganda's biosafety regulatory system should focus on GMOs and not their products. Products from GMOs should be regulated under product-specific statute, not within the biosafety regime.

As a final note, it is important to realize that biosafety regulatory issues in Uganda are likely to increase in importance in the coming years as local scientists develop home grown GMOs . To be ready, therefore, Uganda needs to continuously review its national biosafety regulatory systems and consider the above issues to make it more comprehensive, understandable, workable and fair.

REFERENCES

Cohen, J., Komen, J., and Zambrano, P. 2005. Public GM Innovations and Safety Regulation Environment and Production Technology Division, IFPRI, Washington, D.C. Presentation at The Globalization of Agricultural Biotechnology: Multi-disciplinary Views from the South, March 11-13, 2005.

CONSENT. 2003. First Biotechnology and Biosafety Stakeholders Dialogue Report. Consumer Education Trust, Kampala, Uganda. Report of Meeting held in Kampala, Uganda, on June 18, 2003.

Falck Zepeda, J. and Cohen, J. 2005. Biosafety Regulation of Genetically Modified Orphan Crops in Developing Countries: A Way Forward.

Jaffe, G. 2004. Regulating transgenic crops: a comparative analysis of different regulatory processes. *Transgenic Research*, 13:5-19.

Jaffe, G. 2005. Implementing the Cartagena Biosafety Protocol through National Biosafety Regulatory Systems: An Analysis of Key Unresolved Issues. *Journal of Public Affairs*, 5: 299-311.

Johnston, S., Monagle, C. and Mackenzie, R. 2008. Internationally funded Training in Biotechnology and Biosafety: Is it bridging the biotech divide. United Nations University Institute of Advanced Studies (UNU-IAS).

Kinderlerer, J. 2002. Regulation of Biotechnology: needs and burdens for developing countries. Sheffield Institute of Biotechnological Law & Ethics, University of Sheffield, Sheffield U.K.

Kinderlerer, J. and Adcock, M. 2005. Agricultural Biotechnology, Politics, Ethics, and Policy. In: Were Omamo, S. and von Grebmer, K (eds.).

McLean, M., Frederick, R., Traynor, P., et al. 2002. A conceptual framework for implementing biosafety: Linking policy, capacity, and regulation. ISNAR, The Netherlands.

Nyiira, Z. et. al., 2000. The Uganda National Biosafety Framework.

Pew Initiative on Food and Biotechnology. 2004. Issues in the regulation of genetically engineered plants and animals. Pew Initiative on Food and Biotechnology, Washington, D.C.

The World Trade Organization. 1995b. Technical Barriers to Trade Agreement. http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm on August 3, 2005.

United Nations Environment Programme-Global Environment Facility (UNEP-GEF) Biosafety Unit. 2004. - Phase 3 Toolkit Module Part (I): Developing the Regulatory Regime. UNEP-GEF, Geneva, Switzerland. http://www.unep.ch/biosafety/development/devdocuments/ToolkitBSF3RegEN.pdf

Zarrilli, S. 2005. International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks. United Nations Conference on Trade and Development, United Nations, New York.

4
Biosecurity

OVERVIEW

This section covers the scope of biosecurity. Aspects of laboratory biosecurity include: physical security, personnel management, material control and accountability, and programme management. Covered in this section is biosecurity as it relates to public health, food and agricultural security, and tools for developing a national framework for biosecurity. National frameworks are useful to regulate, manage, and control biosecurity, permitting practical implementation, increasing cost effectiveness, and improving consistency across sectors. Also covered in this section are treaties, agreements, legislation, best practices, guidelines, outreach and education that ensure biosecurity. The topic engaging scientists in biosecurity, discusses the role of the scientists in biosecurity which includes development of courses, information sharing, research (which is very expensive), infrastructure development, and creating avenues for interaction with other scientists. Scientists have the responsibility to actively help mitigate the risk that their scientific efforts might be exploited for the worst consequences. The potential of mycotoxins as chemical warfare agents is discussed and it is advised that the attention generated by this issue should be used to focus attention on the real issues of mortality and morbidity due to mycotoxin exposure from fungal contamination of staple foods in developing countries.

DEVELOPING NATIONAL BIOSECURITY SYSTEMS

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Biosecurity literally means 'safe life' and encompasses all policies and measures taken to secure humans, animals and plants against biological threats regardless of whether they are naturally-occurring or man-made. This includes the prevention, detection and mitigation of damage by disease, pests and bioterrorism to economies, the environment (including water, agriculture and biodiversity) and human and animal health. Biosecurity cannot be defined singularly; rather it is the sum of government policies and programmes; the role of institutions and individuals; the relationship of businesses and bio-responsibility, education and community engagement at the local, national and international levels. Unlike biosafety precautions, biosecurity tends to be active; measures might include systems for accounting and control of pathogens and toxins in laboratories, monitoring statistics for patterns which suggest emerging epidemics, public health education and alertness, widespread use of sophisticated pathogen detectors, and securing distribution and transportation systems for food and agricultural products. Systems for biosecurity can be developed at the national level, but have widespread ramifications. Regional and global trade and transportation, for preventing the spread of transboundary diseases, and environmental protection against invasive species are just a few examples of international biosecurity concerns.

The goals of this paper are to: 1) describe the scope of biosecurity and articulate several key areas for biosecurity concerns, and 2) outline some existing tools and techniques that can be used to improve national systems for biosecurity.

Scope of Biosecurity

The extent of biosecurity measures include the control and protection against biological agents and disease, risk mitigation based on countermeasures and the responsiveness of public health and medical facilities; national and international partnerships and cooperation and last, but not least, those scientific contributions that support efforts to discover, develop and deploy ways and means to minimize or defeat new, emerging or re-emerging biological threats. Several key areas that should be considered include: laboratory biosecurity, human and animal health security, and environmental security.

Laboratory Biosecurity

Laboratory biosafety and biosecurity are often confused; they mitigate different risks, but are complementary and share a common goal: keep biological materials safely and securely inside the areas where they are used and stored. However, the World Health Organization (WHO) describes laboratory biosafety as the containment principles, technologies and practices used to "prevent unintentional exposure to pathogens and toxins, or their accidental release" (WHO, 2006). A culture of biosafety refers to the understanding and routine application of a set of safe practices, procedures, actions and habits that protect the people working with biological materials. In contrast, biosecurity is described as the "protection, control and accountability for biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release" (WHO, 2006). Laboratory biosecurity should be built upon a firm foundation of good laboratory biosafety, and can be promoted through a combination of administrative, regulatory, and physical security procedures, combined with a culture of responsibility and accountability. There are a number of aspects of biosecurity. (Sandia National Laboratories, 2005):

- **Physical Security:** Designed to restrict access to dangerous pathogens and toxins to only authorized personnel; includes security of information that could lead to loss of pathogens or

toxins. This may include graded physical security controls, access controls and emergency response;

- **Personnel Management:** Refers to the suitability and training of an individual for safe and secure management of facilities and/or materials;
- **Material Control and Accountability (MC&A):** Refers to the timely knowledge of what materials exist, where they are, and who is accountable for them;
- **Programme Management:** Laboratory management is responsible for the guidance, implementation, and oversight of a laboratory biosecurity programme. Activities include: identification and prioritization of programme needs, development of a biosecurity plan, and allocation of resources and responsibilities to fulfil the plan.

An important security function, that cross-cuts each of above areas, is information management. The design and maintenance of information management systems is important to control information regarding technologies and research outcomes that have the potential to be used for illicit purposes.

Biosecurity and Public Health

Public health security can be defined as the activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of national populations. Global public health security widens this definition to include acute public health events that endanger the collective health of populations living across geographical regions and international boundaries (WHO, 2007). Health security incorporates preparedness for and protection against: the emergence of new or newly recognized pathogens; the recurrence of well-characterized epidemic-prone diseases; and, the potential for accidental or deliberate release of biological agents.

The challenges of ensuring health security will vary by country and by region, but there are tools, both preventive and responsive, which can be commonly used in all areas. Tools include the promotion of 'health equity', disease surveillance and emergency response.

Health equity is one of the strategic goals of the WHO Health for All in the 21st Century initiative. It refers to the equitable distribution of underlying determinants of health, such as food, nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment. Health inequity is certainly one of the destabilizing influences requiring innovative science, technology, and policy solutions. Promoting health equity is a key element to ensuring public health.

Another proactive public health measure is to mitigate and/or prevent disease outbreaks by strengthening public health surveillance and response activities. Disease surveillance systems provide for the ongoing collection, analysis and dissemination of data to prevent and control disease. Disease surveillance data are used by public health professionals, medical professionals, private industry, and interested members of the general public in numerous ways, including rapid identification and containment of disease, contingency planning and emergency preparedness.

Policies for these tools are established at the national level, but response to public health events begins (and often remains) at the local level. Local, state and regional players are responsible for translating national policies into operational procedures, and determining how a policy will function at local levels will be critical. For instance, the availability of local resources to monitor disease and establish communications may not match standards outlined in national policies. Ensuring communication among government, public health, and hospitals is critical to developing an effective public health system.

Food and Agriculture Security

A third definition of biosecurity focuses on aspects of food and agriculture security. The United Nations Food and Agriculture Organization (FAO) defines biosecurity as the "management of all biological and environmental risks associated with food and agriculture. This includes: ensuring food safety, monitoring the introduction and release of genetically modified organisms (GMOs) and their products, and monitoring the introduction and spread of invasive alien species, alien genotypes, plant pests, animal pests, diseases zoonoses." Food and agriculture security encompasses all policy and regulatory frameworks (including instruments and activities) to manage risks associated with plant health, animal health, and food safety. Characteristics include:

- Protection against the introduction of plant pests and diseases, animal pests and diseases, and zoonoses;
- Sanitary, healthy and secure pasture and water conditions for crops and livestock;
- Protection against environmental degradation; protection of biodiversity;
- Secure and hygienic food processing and packaging facilities;
- Transportation and distribution facilities that provide safe, secure, and timely access to food.

Food and agriculture security is also related to health equity, as it encompasses the security of food supplies, as well as the elimination of hunger and malnutrition. Improved infrastructure, investment in research and development of appropriate technologies, and capacity building in animal husbandry, disease surveillance and emergency response are all tools useful for improving food and agriculture security.

Tools for Developing a National Framework for Biosecurity

Everyone is affected by and can influence biosecurity. However, pivotal players include: national leaders and policy-makers, the scientific research and development community, academic institutions, businesses and individual researchers. The issues reach across all sectors, touching food and agricultural industries, medical, veterinary, and pharmaceutical industries, infrastructure and emergency response, and government organizations.

National frameworks are useful to regulate, manage and control biosecurity, permitting practical implementation, increasing cost effectiveness, and improving consistency across sectors. A variety of tools can be used, including: treaties, agreements, and implementing legislation; best practices and guidelines; and outreach and education. Some of these tools (e.g. treaties, implementing legislation) must be employed at the national level and enforced or enacted at an organizational level. Other tools (e.g. best practices and guidelines, outreach and education) may be best employed at the national, organizational and professional or individual levels.

Treaties, Agreements, and Implementing Legislation

International agreements are crucial to creating normative framework and umbrella under which regional and national non-proliferation efforts can thrive. Two significant agreements in preventing the proliferation of BW are:

- 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. Protocol was negotiated in response to CW use during World War I. However, most countries that ratified prohibited only the first use of such weapons.
- Biological and Toxin Weapons Convention (BTWC or BWC) which was signed in 1972, entered into force in 1975. This is the principal international arms control agreement for BW.

Export control agreements and international legal frameworks also play an important role. Examples of this include:

- Australia Group: The Australia Group that was formed in 1985 in response to the use of CW in the Iran-Iraq war; currently includes 39 nations plus the European Commission. It acts as a working advisory group to BTWC. It also has harmonized common export controls for BW non-proliferation, and developed common control lists for agents and toxins and dual-use equipment.
- Wassenaar Arrangement: Established in 1995, the Wassenaar Arrangement is a voluntary association of 33 states who have agreed on "non-binding" best practices regarding export controls for conventional arms and dual-use goods and technologies. In 2001, scope extended to include preventing acquisition by terrorist groups and organizations as well as by individual terrorists.
- UNSCR 1540: Imposes binding obligations on all States to establish domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, and their means of delivery, including by establishing appropriate controls over related materials. It also encourages enhanced international cooperation on such efforts, in accord with and promoting universal adherence to existing international non- proliferation treaties.

National legislation can be used to implement the tenets of international treaties and agreements, and to issue additional national guidance. Some examples of legislation issued in the United States include:

- USA PATRIOT Act of 2001: Criminalizes possession of BW;
- Bioterrorism Preparedness Act of 2002: Establishes Select Agents (Human, Plant, Animal); requires registration of facilities that work with select agents; regulates transfers of select agents; requires background checks for personnel

- Pandemic and All-Hazards Preparedness Act of 2006: Establishes a national organization for health preparedness and response; facilitates funding for state and local organizations in case of health emergencies; provides for review and improvement of medical surge capacity; establishes and R&D organization to improve and facilitate development of advanced countermeasures

Best Practices and Guidelines

A number of national and international organizations have developed guidelines and best practices designed to provide guidelines and share best practices of biosafety and biosecurity, as well as risk assessment and mitigation tools.

- World Health Organization (WHO) Laboratory Biosafety Manual and Biosecurity Guidance: the WHO offers a laboratory biosafety manual which was developed as a reference to nations developing national standards or codes of practice. It has also provided biosecurity guidelines, in a booklet entitled 'Biorisk Management: Laboratory Biosecurity Guidance'.
- Centers for Disease Control (CDC) BMBL Guidelines: the CDC offers the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidelines. The BMBL guidelines address laboratory safety procedures for handling infectious agents and describe laboratory safety standards for Biosafety Levels 1-4, but do not specifically address laboratory security issues
- American Society of Microbiology (ASM): the ASM has developed a number of biosecurity tools and practices, including a Code of Scientific Ethics and a review process to assess dual-use security concerns in publications.

Outreach and Education: Individual Responsibility in Promoting Biosecurity

Article IV of the BWC implies that states must hold their citizens responsible for violating the BWC, thus providing support for the concept of individual responsibility. Due to the increasing dual-use nature of research in the life sciences, upholding the "intent" of the BWC and other international non-proliferation efforts will increasingly rest upon the expertise judgment and goodwill of individual scientists. In fulfilling its BWC obligations, the USG has passed a body of national implementing legislation holding individuals criminally liable for violations.

However, science has traditionally been treated as value-neutral, which means individuals are often unaware of the dual-use concerns related to biological research. There is growing consensus among scientists and policy-makers that awareness and education are among the most effective tools for promoting responsible research and enhancing biosafety and biosecurity. To this end, the U.S. Department of Energy (DOE) has been pursuing education and outreach activities designed to address U.S. obligations for national laboratory scientists under the BWC. The long-term goal would be to develop a "culture of responsibility" that would include a shared general awareness of security concerns

Conclusion

Biosecurity encompasses all policy and regulatory frameworks (including instruments and activities) to manage risks associated with food, agriculture (including relevant environmental risks) and public health. While many tools exist to enhance biosecurity, developing and implementing appropriate tools will be a challenge. Critical factors in ensuring success will include: 1) Communication among the scientific community, policy-makers, and the business sector so that appropriate laws and guidelines are recognized and followed, 2) Coordination among public health, agriculture, veterinary, and emergency response communities in order to maximize the use of resources, and 3) Capacity

Building – including training, education, funding, and technology deployment – to ensure that the necessary knowledge and resources are available.

REFERENCES

Sandia National Laboratories. 2005. Chemical and Biological Weapons Nonproliferation Department, Laboratory Biosecurity Implementation Guidelines.

World Health Organization, 2006 (WHO/CDS/EPR/2006.6, September 2006). Biorisk Management: Laboratory Biosecurity Guidance.

WHO.2007.World Health Report: A Safer Future - Global Public Health Security in the 21st Century.

ENGAGING SCIENTISTS IN BIOSECURITY: AN AFRICAN PERSPECTIVE

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We live at a time when the global community has become increasingly concerned about infectious disease threat to humans of epidemic and pandemic proportions. Some of these are naturally occurring (Hsuch and Yang, 2003) while others are man-made. However, fast- moving naturally-occurring diseases present the most worrying threats. This calls for a concerted effort not only towards understanding of the infective process of these disease agents but also their prevention, containment and effective treatment.

Biosafety can be defined as a measure to reduce or eliminate exposure of laboratory workers or other persons and the outside environment to potentially hazardous agents involved in microbiological or biomedical facility research (Reynolds M. Salerno and Jennifer G.

Koelm, 2002). As a term, it encompasses the prevention and mitigation from diseases, pests, and bioterrorism in areas that include the economy, environment and public health. This, by extension, will include food and water supply, agricultural resources and production, pollution management, blood, and blood products supplies. Further, biosecurity warranty attempts to ensure that ecologies sustaining either people or animals are maintained. This may include natural habitats as well as shelter, productive enterprises and services, and deals with threats such as biological warfare or epidemics. Biosecurity is now an area that attracts tremendous international attention due to its ramification in all aspects of human existence.

Biosecurity covers a wide spectrum of concerns including but not limited to (*Biosecurity News*, September 2007):

- The development and use of biological weapons by state and non-state actors;
- Safety and security risks of research on pathogenic micro-organisms;
- Codes of conduct for life scientists;
- International law and domestic regulation particularly their impact on research;
- Relevance and application of new technologies to bioscience challenges; and
- Ethical, legal and social dimension of biosecurity – This begs the question: What are society's expectations of its scientists in this aspect?

The Role of Scientists

To successfully engage a scientist within the African context is a challenge because of the following factors:

- Most scientists would have had a limited exposure to high security facilities which will in turn limit their view of this subject; and
- The scientist with regard to being an academic develops a

theoretical approach while exploring opportunities of imparting acquired knowledge to students and colleagues through various means. Such opportunities include the development of course materials and information sharing in a structured way through formal lectures and practice demonstrations.

However, this in itself presents challenges such as access to information which is hampered by several factors, including:

- Computer literacy – with the current trend in e-mode of delivering lecture materials, this has become an important aspect in remaining relevant;
- Access to computers;
- Level of available internet connectivity and wireless technology for free access to services based on these technologies.

This area of research is where the greatest opportunities exist with expenditures running into billions of dollars. For example, in 2004 it was projected that the United States would spend USD 6 billion in 10 years to develop counter measures against biological and chemical weapons (Khan, 2004; Hitt, 2004). It was further noted that much of this research would be done in academic settings throughout the US (Khan, 2004).

Opportunities include:

- Engaging in research that has potential of impacting positively on the society. The dual nature of research in this area constantly raises a red flag;
- Postgraduate training/capacity building – this is extremely important because no meaningful involvement will be achieved if the scientists feel ill-equipped to handle issues of biosecurity;
- Infrastructure development – this creates a serious constraint in carrying out research in this areas; and
- Creating avenues to interact with other scientists – the present workshop is an excellent example.

The greatest challenge that hampers research is the simple fact that the material and infrastructure required to conduct research on biological agents, with a potential use as weapons of mass destruction in bioterrorist acts is well beyond most countries (Jaax, 2005; BioscienceAlert, 2008). The scientists in these regions that cannot participate effectively in research in this area feel marginalized and seriously disadvantaged in on-going endeavours.

While the role of the (African) scientists remains the same irrespective of their physical location, their possible engagement in active research and participation in policy initiatives hinges squarely on the level of competence and a critical mass of high-level manpower that facilitates collaborative efforts. Fruitful engagement will be through traditional and innovative ways including:

- Workshops such as the current one – it is a start but has very limited audience. A move must be made to reach more scientists through institutional-based seminars;
- Travelling workshops for first-hand exposure to facilities and demonstrations;
- An Open forum – a model exists in Kenya. the Open Forum in Agricultural Biotechnology – that provides a monthly forum for stakeholders to share experiences and emerging issues;
- Linkages that forge collaboration of both South-South and South-North. Funding agencies are increasingly leaning towards consortia of research groups. However, it takes time and money to build successful teams. The multi-disciplinary nature of biosecurity research makes it mandatory to work as teams;
- Facilitation to carry out research, including laboratories; the importance of having well equipped facilities cannot be over-emphasized in an era of bioterrorism and development of weapons of mass destruction (WMD); and the institutional framework to support research such as functional Bioethics/ Biosafety Committees, IPR; and

- Establishing links to relevant arms of government and private sector to enable full utilization of research outputs. This will help to build confidence among the industry, set up incubation centres, and establish Centres for Excellence in identified areas according to strength.

Conclusion

Due to the sensitivity surrounding issues of biosecurity only highly competent scientists can be involved in any serious activity in this area; and until we build a critical mass of such scientists no meaningful engagement can be achieved. Any that might exist will be working in isolation which will create mistrust and enhance the 'guinea pig' scenario. These efforts will also not be sustainable.

Scientists must realize and appreciate that they have a responsibility to actively help to mitigate the risk that their sincere scientific efforts might be exploited for the worst consequences. Scientists, at the very least, must educate themselves about these risks.

REFERENCES

BioscienceAlert: http://www.sciencealert.com.au/features/20080802–16875.html

Biosecurity News, Issue 2 September 2007. Centre for Biosecurity, the Australian National University.

Hitt, N.D. 2004. Moving on up: upgrading from BSL2 to BSL3 facility. *Lab Anim*, 33 (10): 7-19

Hsuch, P.R. and Yang, P.C. 2003. Severe Acute Respiratory Syndrome (SARS) – an emerging infection of the 21st century. *Formos Med Association* 102 (12):825-839.

Jaax, J. 2005. Administrative issues related to infectious disease research in the age of bioterrorism. *ILAR*, 46 (1):8-14

Kahn, L.H. 2004. Biodefense research: Can secrecy and safety coexist? *Biosecur Bioterror* 2 (2):81-85

Pastel, R.H, Demmin, G, Severson, G, Torres-Cruz R, Trevino, J, Kelly J., Arrison, J. and Christman, J. 2006. Clinical laboratories, the select agent programme, and biological surety (biosurety). *Clin Lab Med*, 26 (2):299-312

Reynolds, M. Salerno and Jennifer G. Koelm. 2002. Biological Laboratory and Transportation Security and The Biological Weapons Convention prepared for National Nuclear Security Administration Office of Non-proliferation Policy (NA-241) U.S. Department of Energy, available online at: http://www.cmc.sandia.gov/cmc-papers/sand2002-1067p.pdf.

THE POTENTIAL OF MYCOTOXINS AS CHEMICAL WARFARE AGENTS

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Mycotoxins are secondary metabolites of a range of filamentous fungi and are known to contaminate a wide variety of food products around the world. Historically, they are thought to have been implicated in human deaths for over 2 millennia and the outbreaks of ergotism in Europe in the middle ages have been well characterized (Marasas and Nelson, 1987a). More recently, thousands died in the former USSR during World War II from a haemorrhagic syndrome known as Alimentary Toxic Aleukia, caused primarily by T-2 toxin produced by *Fusarium sporotrichioides* and *F. poae* contaminating cereal over-wintered in fields (Marasas and Nelson, 1987b). The deaths of thousands of turkeys in the UK in 1960 in an outbreak of a previously unknown mycotoxicosis termed Turkey-X Disease led to the discovery of the aflatoxins and an increased research effort into all aspects of mycotoxins, especially those occurring naturally in human food and animal feed

Chemical Warfare Incidents Related To Mycotoxins

The Yellow Rain Controversy

The concept of mycotoxins as chemical warfare agents did not appear until the late 1970s during the wars in south East Asia (Tucker, 2001). During the Vietnam War, the US Central Intelligence Agency (CIA) had recruited among tribesmen in northern Laos to help fight North Vietnamese forces and their communist Pathet Lao allies. After the end of the Vietnam War and the final capture of Saigon by North Vietnamese forces in 1975, attention in the region shifted over the period 1975-1981 to North Vietnamese suppression of resistance in Laos and ultimately the invasion of Cambodia to depose the Khmer Rouge regime under Pol Pot. During this period, reports began to emerge of chemical warfare attacks by Vietnamese forces, presumably backed by the USSR. Refugees from the Hmong villages and from Cambodia reported being attacked from the air with an oily yellow liquid, which they called yellow rain. The effects attributed to yellow rain included a wide variety of symptoms such as vomiting, eye pain, headache, coughing, diarrhoea, blistering skin, seizures and other neurological symptoms, and bleeding from nose and gums. Such symptoms did not correlate with known chemical weapons and a hypothesis was put forward that the symptoms were similar to the effects of trichothecene mycotoxins, specifically T-2 toxin. Samples were sent to a laboratory in the USA and some were found to contain the trichothecenes nivalenol, deoxynivalenol and T-2 toxin. The outcome of these investigations was an accusation in 1981 by the US Secretary of State, Alexander Haig, that the USSR was supplying mycotoxins to its Vietnamese and Laotian allies for use in chemical warfare (Tucker, 2001).

T-2 toxin is a group A trichothecene produced mainly by *Fusarium sporotrichioides* and *F. poae*, which may occur on cereals and grasses in the temperate and cold areas of the world (Marasas et al. 1984). It is a potent inhibitor of protein, RNA and DNA synthesis and its toxic effects include digestive disorders, haemorrhage in many organs, oral

lesions, dermatitis, leukopenia, and blurred and painful vision, i.e. many of the symptoms reported by Hmong and Cambodian refugees.

The controversy over yellow rain became more intense with further scientific investigation of the claims that it was a chemical warfare agent (Tucker, 2001). Samples of yellow rain, examined under the microscope, showed that it consisted mainly of pollen, that the type of pollen was characteristic of plants indigenous to south East Asia and that the shape, size, colour, texture and pollen content were identical to droppings of South East Asian honey bees. The pollen grains were hollow, indicating digestion by bees. In addition, the natural phenomenon of collective cleansing flights, which results in a shower of yellow faeces, has been observed in China, Thailand and recently near Calcutta in India (Tucker, 2001; 2002). Further controversy arose over the chemical analyses when other laboratories in UK, USA, France and Sweden failed to confirm the original reports of the presence of trichothecenes in yellow rain.

The exact nature of yellow rain incidents and the events in Laos and Cambodia during the late 1970's remain controversial and may never be fully resolved.

Aflatoxin and Iraq

The aflatoxins, of which aflatoxin B_1 is the most abundant and most toxic, are produced mainly by *Aspergillus flavus* and *A. parasiticus* on a wide range of food commodities, including maize, wheat and nuts. The toxins can be produced in the field prior to harvest, or alternatively, can arise due to fungal growth under poor storage conditions. Exposure to high levels of aflatoxin can result in acute human aflatoxicosis leading to jaundice, oedema, GI haemorrhage and ultimately, death. Apart from these acute effects, aflatoxins have a wide range of negative health consequences and have been shown in many studies to be hepatotoxic, teratogenic, mutagenic, genotoxic and hepatocarcinogenic. Of the literature that details the adverse effects of aflatoxins, most notable is the data on hepatotoxicity and hepatocarcinogenicity in a variety of

animal species and the human epidemiological evidence of an association between aflatoxin exposure and primary liver cancer (IARC, 1993; 2002). Other human health concerns are the association between aflatoxin exposure and growth retardation and stunting in children (Gong et al., 2004), immune suppression in exposed populations (Pestka and Bondy, 1994; Jiang et al., 2005) and the possible causal role it plays in kwashiorkor (Hendrickse, 1991).

Unlike T-2 toxin which acts directly and rapidly on the organism, aflatoxin requires prior metabolism in the liver and many of its poisoning effects are not of an immediate nature. For this reason, aflatoxin was not generally considered as a suitable agent for chemical warfare until it was discovered that large quantities had been prepared in Iraq prior to the first Gulf War (Augerson, 2000). Facts revealed to UN inspectors, which could not however, be independently verified, included the assertion that aflatoxin was produced on cultured rice and that a total quantity of 2200 L of crude aflatoxin mixture of unknown concentration or composition was prepared. Some of this was loaded into Scud warheads and various bombs and rockets. The munitions were never deployed. Nevertheless, it has been surmised that aflatoxins, released during military strikes on chemical storage sites during the war, may have been a contributing factor in the symptoms reported by Gulf War veterans (Augerson, 2000).

Mycotoxins as Chemical Warfare Agents

Apart from the toxins mentioned above, only the group A trichothecene diacetoxyscirpenol (DAS), which would induce similar effects to T-2 toxin, appears to have elicited specific mention as a chemical warfare agent (US Dept. of Defense 1997). The potential weaponization of mycotoxins raises a number of issues. Firstly, it is necessary to consider the toxicities of mycotoxins versus other toxins and more generally known chemical warfare agents.

Table 4.1: Toxicities of various chemicals, toxins and chemical warfare agents

Table 4.1: Toxicities of various chemicals, toxins and chemical warfare agents

Toxin	Exposure Route	Animal	LD_{50} (mg/kg bw)	Reference
Sodium cyanide	oral	Rats	15	Merck Index 1989
Aflatoxin B_1	intra peritoneal	Mice	9.5	Merck Index1989
Mustard gas	intra venous	Rats	3.3	Merck Index 1989
T-2 toxin	intra peritoneal	Rats	0.9-2.2	Canady et al. 2001
	inhalation	Rats	0.05	Canady et al. 2001
Sarin gas	intra peritoneal	Mice	0.42	Merck Index 1989
Ricin	oral	Mice	20	Augerson 2000
	subcutaneous	Mice	0.024	Augerson 2000
	inhalation	Mice	0.003-0.005	Augerson 2000
TCDD*	oral	Rats	0.022-0.045	Merck Index 1989
VX gas	subcutaneous	Rabbits	0.015	Merck Index 1989
Botulinum toxin	inhalation	Humans	0.000002	Horowitz 2005

* 2, 3, 7, 8-tetrachlorodibenzo-*p*-dioxin

Table 4.1 shows a list of LD_{50} values for a selection of these chemicals. Whereas it is recognized that these values vary greatly between animal species and with the route of exposure, and may not be relevant to the battlefield situation, they give an indication of the relative potencies of the various agents. As a point of universal reference, the table includes sodium cyanide. The table shows that aflatoxin B_1, the most potent of

the aflatoxin analogues, and T-2 toxin, together with mustard gas, a blistering agent used in the First World War, are of the same order of toxicity as sodium cyanide. T-2 toxin causes painful and severe skin and eye irritation. It is about 400 times more efficient as a blister agent than the sulphur mustards, of which mustard gas is an example (US Dept. of Defense, 2001). The more recently developed synthetic nerve gases, sarin gas and VX gas, generally have far greater toxicity, especially if compared with aflatoxin B_1. TCDD (2,3,7,8-tetrachlorodibenzo-*p*-dioxin) is the most toxic member of the group of polychlorinated dibenzodioxins, which are chemical contaminants produced in a range of industrial processes. It is well known as the contaminant of Agent Orange, a herbicide used by the USA during the Vietnam War, which was implicated as the causative agent of various symptoms suffered by exposed individuals. Ricin, which is a protein extracted from the castor bean and has a long history of accidental and intentional poisoning, and botulinum toxin, a protein from the bacterium *Clostridium botulinum*, are orders of magnitude more toxic than aflatoxin. Clearly based on toxicities, other agents appear more potent for military purposes than these mycotoxins.

In considering the use of mycotoxins as chemical warfare agents, it is necessary to consider other issues such as the need for large-scale bioreactors for their production, the problem of delivery as they are non-volatile solids which require dispersal as aerosols, their effectiveness as compared to nerve gas, and the difficulty in delivering an incapacitating or lethal dose on the battlefield. For all the above reasons, there has been little military interest in mycotoxins, although fears remain that they could be used as a terrorist weapon.

Mycotoxins as a Food Safety Issue

The mycotoxins may not be a serious military issue, but they remain a potent natural contaminant of human foods. Of the mycotoxins discussed above, T-2 toxin and DAS are generally associated with cereal crops of the temperate and colder regions, whereas aflatoxin is an ubiquitous contaminant of staple foods in many areas of the world, especially

developing countries. There have been various reported episodes of human aflatoxicosis (acute human poisoning from aflatoxin) in Africa, including a recent outbreak in the eastern and central provinces of Kenya in 2004 in which over 120 people died (Nyikal et al., 2004). Aflatoxin levels in maize collected in affected areas were found to be as high as 46.4 mg/kg (Lewis et al., 2005). Tragic as these figures are, they can be considered to be no more than the ears of the hippopotamus. Besides the cases presented at hospitals, it can be expected that others were not diagnosed or did not present at a hospital. Many more, not showing signs of acute poisoning, will suffer the consequences of exposure in the form of increased incidence of liver cancer. An even larger cohort, including others in many African countries where high aflatoxin contamination is prevalent, may suffer from morbidity due to the malnutrition, growth impairment and immune suppression caused by chronic exposure to this toxin. The extent to which these factors influence the burden of disease in developing countries is difficult to quantify, but is undoubtedly significant (Shephard, 2008).

A recent publication has highlighted an ironic situation by juxtaposing possible deaths due to toxin exposure with the attention generated. Whereas mycotoxins as chemical warfare agents have generated very high interest, but probably few (if any) deaths, the deaths due to liver cancer in developing countries attract intermediate interest and those due to the chronic effects of growth impairment and immune suppression, which may be estimated in the many thousands, achieve little to zero attention (Wild, 2007).

Conclusion

Whereas yellow rain remains a controversial issue and the exact reasons for the development of aflatoxin solution as a chemical weapon in Iraq are unclear, mycotoxins are more generally considered not to be useful in chemical warfare. However, the attention generated by this issue should be used to focus attention on the very real issues of mortality and morbidity due to mycotoxin exposure from fungal contamination of staple foods in developing countries.

REFERENCES

Augerson, W. 2000. A review of the scientific literature as it pertains to Gulf War illnesses. Volume 5: Chemical and biological warfare agents. Chapter 4: Toxins. Http://www.rand.org/pubs/monograph_reports/MR1018.5/MR1018.5.chap4.html (Accessed 25 February 2008).

Canady, R.A, Coker, R.D, Egan, S.K, Krska R., Olsen, M., Resnik, S., Schlatter J. 2001. T-2 and HT-2 toxins. In: Safety Evaluation of Certain Mycotoxins in Food. WHO Food Additives Series 47, FAO Food and Nutrition Paper 74, Prepared by the 56th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Geneva: WHO. pp 557-680.

Gong, Y.Y., Hounsa, A., Egal, S., Turner, P.C., Sutcliffe, A.E., Hall, A.J., Cardwell, K., Wild, C.P. 2004. Postweaning exposure to aflatoxin results in impaired growth: A longitudinal study in Benin, West Africa. Environmental Health Perspectives 112:1334-1338.

Hendrickse, R.G. 1991. Clinical implications of food contaminated by aflatoxins. Annals of Academic Medicine 20:84-90.

Horowitz, B.Z. 2005. Botulinum toxin. Critical Care Clinics 21: 825-839.

IARC. 1993. International Agency for Research on Cancer. WHO IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Some Naturally Occurring Substances: Food Items and Constituents, Heterocyclic Aromatic Amines and Mycotoxins. Aflatoxins. Lyon: IARC. 56:245-395.

IARC. 2002. International Agency for Research on Cancer. WHO IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene. Aflatoxins. Lyon: IARC. 82:171-274.

Jiang, Y.I., Jolly, P.E., Ellis, W.O., Wang, J-S, Phillips, T.D., Williams, J.H. 2005. Aflatoxin B1 albumin adduct levels and cellular immune status in Ghanaians. International Immunology 17: 807-814.

Lewis, L., Onsongo, M., Njapau, H., Schurz-Rogers, H., Luber, G., Kieszak, S., Nyamongo, J., Backer, L., Dahiye, A.M., Misore, A., DeCock, K., Rubin, C., and the Kenya Aflatoxicosis Investigation

Group. 2005. Aflatoxin contamination of commercial maize products during an outbreak of acute aflatoxicosis in eastern and central Kenya. Environmental Health Perspectives 113:1763-1767.

Marasas, W.F.O., Nelson, P.E. 1987a. Ergotism. In: Mycotoxicology. University Park, PA, USA: The Pennsylvania State University Press. pp 19-24.

Marasas WFO, Nelson PE. 1987b. Hemorrhagic Syndrome. In: Mycotoxicology. University Park, PA, USA: The Pennsylvania State University Press. pp 41-44.

Marasas, W.F.O., Nelson, P.E., Toussoun, T.A. 1984. Section Sporotrichiella. In: Toxigenic Fusarium Species. University Park: The Pennsylvania State University Press. pp 12-91.

Merck Index. 1989. 11th Edition. Rahway, NJ, USA: Merck & Co. Inc.

Nyikal, J, et al. 2004. Outbreak of aflatoxin poisoning - eastern and central provinces, Kenya, January - July 2004. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, September 3 2004. 53(34): 790-793.

Pestka, J.J., Bondy, G.S. 1994. Immunotoxic effects of mycotoxins. In: Miller, J.D., Trenholm, H.L., editors. Mycotoxins in grain. St. Paul: Eagan Press. pp 339-58.

Shephard, G.S. 2008. The Impact of Mycotoxins on Human Health in Developing Countries. Food Additives and Contaminants 25: 146-151.

Tucker, J.B. 2001. The Yellow Rain controversy: Lessons for arms control compliance. The Nonproliferation Review. Spring 2001: 25-42.

Tucker, J.B. 2002. Conflicting evidence revives TheYellow Rain controversy. Online available at: www.cns.miis.edu/pubs/week/020805.htm (Accessed 26 February 2008).

US Dept. of Defense. 1997. CBWs Chemical and biological weapons tested. Online available at: www.uhuh.com/weapons/chem-bio.htm (Accessed 25 February 2008).

US Dept. of Defense. 2001. Close-out Report: Biological Warfare Investigation. Online available at: www.gulfink.osd.mil/bw_ii/index.html (Accessed 25 February 2008).

Wild, C.P. 2007. Aflatoxin exposure in developing countries: the critical interface of agriculture and health. Food and Nutrition Bulletin 28: S372-S380.

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5
Building a Coalition

OVERVIEW

The Academy of Science of South Africa is proposing to deal with issues of biosecurity through a biosecurity standing committee to look at the wider context within life sciences and health issues. This committee would also convene experts in the life sciences and health issues. Also discussed in this section is how to improve oversight through the development of an educational module in the West and in Africa. The importance of education and awareness-raising is emphasised in this regard. Biosafety and biosecurity education should not only be for those associated with life sciences but also those involved in ethics and responsible research practice, international law obligations of their governments, especially those related to Biological Trade and Weapons Convention. Education, in addition to legal issues, has been identified as a vital component in achieving enhanced systems of research governance that address dual-use knowledge and techniques. The most important thing is to educate students and young researchers about the dangers of dual-use research and highlight educational initiatives taken to date**.** The subsequent discussion session mentioned that as the dual use modules are built, it maybe important for scientists to try and communicate whatever they are doing to the public. It would be ideal for each activity and course to have an element of communication and information dissemination. The workshop participants expressed concern that the dual use course module was not receiving as much support from scientists and policymakers as it should. In line with this,

the Uganda National Council for Science and Technology, as a body that oversees research and advises government on science and technology policies, expressed their willingness to work out mechanisms to promote the dual use course module

BIOSECURITY INITIATIVE BY THE ACADEMY OF SCIENCE OF SOUTH AFRICA – A PROPOSAL FOR THE ESTABLISHMENT OF A STANDING COMMITTEE

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The Academy of Science of South Africa (ASSAf) was initiated by scholars and scientists from all sectors of South Africa and was launched as a voluntary association in 1996, with the then South African President Nelson Mandela as the patron of the launch. In 2001 the Academy was formally established and recognized by the state with the passing of the Academy of Science of South Africa Act No. 67 of 2001 by the Parliament. The Act gave ASSAf the status of being an official national science academy, recognized by the government and representing South Africa in the international community of science academies.

The vision of the Academy is to be the apex organization for science and scholarship in South Africa, internationally respected and connected, its membership simultaneously the aspiration of the country's most active scholars in all fields of scientific enquiry and the collective resource, making possible professionally the managed generation of evidence-based solutions to national problems.

ASSAf is obliged by paragraph 3(d) in its Act (No. 67, 2001) to "provide effective advice and facilitate appropriate action in relation to the collective needs, opportunities and challenges of all South Africans". Paragraph 13(1a) reads that the Academy may "at the request of any person or on its own initiative, investigate matters of public interest concerning science and on the strength of the findings act in an opinion-forming and advisory manner".

Through its already established capability and achievements, coupled with its future capacity-building efforts, ASSAf has coordinated national and international workshops and published peer-reviewed reports such as 'Evidence-based Practice', the IAP regional Workshop on 'Water Research in Africa', 'A Strategic Approach to Research Publishing in South Africa', 'Science-based Improvements of Rural/Subsistence Agriculture', and 'Nutritional Influences on HIV/AIDS and TB'. The ongoing evidence-based studies include a consensus study on clinical research, and standing committees on science for poverty alleviation and enhancement of science education in South Africa. The proposed studies include postgraduate study, the status of the humanities in South Africa, and there may be a biosafety/biosecurity standing committee.

The debate on biosecurity issues in South Africa was initiated after ASSAf became the signatory of the Biosecurity Statement which was released in November 2005. Towards the end of 2006, ASSAf received a questionnaire from IAP on the national impact of biosecurity initiatives which was supposed to be completed annually by all the signatories of the Biosecurity Statement. When the first questionnaire was completed in 2006, not much was done by ASSAf apart from being a signatory of the statement. It was against this background that the Academy deliberated on this matter to determine how the Academy could sensitize the country to biosecurity recommendations as listed on the statement.

The discussions were held by the Academy and the outcome included:

1. Placing the statement on the ASSAf website;
2. Disseminating the statement to Academy Members, government departments and stakeholders;
3. Distributing annual questionnaires to targeted institutions and individuals, to determine whether they were implementing the recommendations of the statement;
4. Organise workshops and symposiums on topics related to biosecurity issues;

5. Set up a task team to review South African regulatory frameworks and determine whether they cover issues pertaining to biosecurity and advice on the necessity of developing a biosecurity code of conduct.

After the deliberations by the Academy staff, the first three items were achieved. A proposal was presented for the fourth item in the form of ASSAf hosting a biosecurity symposium. Based on the advice received from the ASSAf Council meeting in August 2007, a proposal for the establishment of Biosecurity Standing Committee was developed and presented to the ASSAf Council on 7 March 2008. The proposal focused on the following issues:

- Increasing awareness of dual-use research and the responsibilities of scientists in preventing the misuse of science for hostile purposes;
- Developing an understanding of biosecurity issues in the context of Africa, and in particular South Africa;
- Evaluate and report on existing national biosafety and biosecurity measures;
- Develop proposals regarding additional oversight mechanisms, if these are deemed to be necessary;
- Consider existing risk assessment and management tools to respond to accidental and deliberate epidemics;
- Evaluate existing mechanisms for regional collaboration and co-operation to control and prevent the deliberate, natural or accidental spread of infectious disease;
- Make recommendations to government and the scientific community on biosecurity issues needing attention;
- Develop proposals for events such as workshops, symposiums, consensus panels etc to enable scholars to deliberate on biosecurity issues.

The ASSAf Council noted that the proposal has placed much emphasis on bioterrorism and biological warfare and less on epidemics and

emerging pathogens which are devastating Africa, South Africa included. The Council resolved that biosecurity issues, as depicted in the proposal, were not top priority for South Africa. The ASSAf Project Officer was mandated to rework the proposal and focus on the South African challenges such as bioethics, biosafety and other biorisks common in the country rather than bioterrorism and weapons of mass destruction. The Council concluded that the proposal should be brought to the next Council meeting in May 2008 with more focus on health safety issues which are at the core of challenges facing South Africa and Africa as a whole.

The next step for ASSAf is to:

a) rework the draft proposal for a standing committee which will look at a wider context within life sciences and health issues;
b) Based on approval by the ASSAf Council, organise a meeting for South African experts on plant science, animal science, biotechnology, nanotechnology and other sciences.

REFERENCES

Academy of Science of South Africa. 2001. Academy of Science of South Africa Act.

IMPROVING OVERSIGHT: DEVELOPMENT OF AN EDUCATIONAL MODULE ON DUAL-USE RESEARCH IN THE WEST

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The 'dual-use' potential of life science research has been a topic of increasing attention in recent years as part of the growing concern about the inadvertent or deliberate spread of disease. While 'dual-use' functions as an umbrella phrase, one sense of it refers to the possibility that 'the generation and dissemination of scientific knowledge could be misapplied for biological weapons development and production' (Atlas and Dando, 2006). Major studies of this sense of the term include the US National Research Council (NRC) and Institute of Medicine's (IOM) report *Biotechnology Research in an Age of Terrorism*, the NRC's *Globalization, Biosecurity, and the Future of the Life Sciences*(NRC and IOM, 2004), and the British Royal Society's *Scientific and Technological Developments Relevant to the Biological & Toxin Weapons Convention* (McLeish and Nightingale, 2005). Echoing sentiments elsewhere, these analyses have underscored the breadth and scale of challenges in preventing the destructive application of the life sciences.

Education and Awareness-raising

The call for greater education of those associated with the life sciences has been prominent in policy proposals in the West and elsewhere (Centre for Applied Philosophy and Public Ethics, 2006). Over the past several years, international bodies such as the UN Policy Working Group on the United Nations and Terrorism, national organizations such as the British Medical Association, and international agencies such as the International Committee of the Red Cross, have made calls for the enhanced education of scientists, administrators, physicians, and others

about the potential for destructive application of bio- and medical sciences (UN, 2002; British Medical Association, 2002; ICRC, 2004).

Many of the calls have been couched in terms of promoting ethical decision-making. For instance, the 2002 World Medical Association's *Declaration of Washington on Biological Weapons* contends that as part of fostering the necessary ethos in biomedical research, those associated with it have "a moral and ethical obligation to consider the implications of possible malicious use of their findings"(World Medical Association, 2002).

A report from a 2006 Royal Society, InterAcademy Panel (IAP), and International Council for Science (ICSU) workshop proposed that researchers and students should be educated by "perhaps by undertaking courses in ethics and responsible research practice, and should be taught about relevant international law obligations of their governments, especially relating to the BTWC (Biological and Toxin Weapons Convention). Bioethics curricula should build on local values and ethical norms" (Royal Society, 2006).

This reference to legal obligations signals the compliance function that can be sought from education. A 2004 Royal Society and the Wellcome Trust meeting concluded that "education and awareness-raising training are needed to ensure that scientists at all levels are aware of their legal and ethical responsibilities," and that such training was rare in the UK (Royal Society and Wellcome Trust, 2004). The 2005 IAP *Statement on Biosecurity* maintains that scientists "should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research"(IAP, 2005).

However, many concerns about dual-use research knowledge and techniques extend beyond legal and regulatory compliance. Education has been identified as a vital component in achieving enhanced systems of research governance that address dual-use knowledge and techniques.

In *Globalization, Biosecurity, and the Future of the Life Sciences*, the NRC and IOM Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats argued that it was prudent to establish a "decentralized, globally distributed, network of informed and concerned scientists who have the capacity to recognize when knowledge or technology is being used inappropriately or with the intent to cause harm" (NRC, 2006).

In 2005 the UK Biotechnology and Biological Sciences Research Council, Medical Research Council and Wellcome Trust released *Managing Risks of Misuse Associated with Grant Funding Activities* (Wellcome Trust, 2008). Later that year the Wellcome Trust released *Guidelines on Good Research Practice* which stated that "institutions should have in place mechanisms to ensure that risks of misuse associated with ongoing research programmes are identified and managed, and to provide advice to the researchers that they employ on these issues" (Wellcome Trust, 2005). How and what advice institutions should supply, though, was left unspecified. It is unclear that any activities have been undertaken on a UK-wide basis, let alone an international one, that could adequately underpin this recommendation.

The first recommendation of *Biotechnology Research in an Age of Terrorism* was that "national and international professional societies and related organizations and institutions create programmes to educate scientists about the nature of dual-use dilemma in biotechnology and their responsibilities to mitigate its risks" (NRC, 2003). In 2005 the National Science Advisory Board for Biosecurity (NSABB) was charged with developing recommendations on "mandatory programs for education and training in biosecurity issues for all scientists and laboratory workers at federally-funded institutions" (NSABB, 2006a). While critical of certain possibilities that might stem from the mandate of NSABB, an editorial in *New Scientist* argued that "the most important thing…is to educate students and young researchers about the dangers of dual-use research" (*New Scientist*, 2006).

The 2007 *Report of the NSABB Working Group on Oversight Framework Development* repeatedly identified education and raising awareness as crucial prerequisites for proper oversight. The importance of education derived from the emphasis placed on investigators to assess the dual-use dimensions of their own work. Although the strategies outlined by NSABB left many of the exact details of the oversight systems to be worked out by institutions, the overall call is primarily for lead scientists to determine whether their work falls into the category of 'dual-use research of concern,' assess its risks and benefits, propose communication strategies, and undertake other responsive efforts for minimizing identified risks. As a result of this devolved approach, NSABB contended "an enhanced culture of awareness is essential to an effective system of oversight and is a critical step in scientists taking responsibility for the dual-use potential of their work" (NSABB, 2007). Related to this point, a 2007 National Research Council report titled *Science and Security in a Post 9/11 World* recommended that "To strengthen and harmonize the institutional review of life sciences research, the Department of Health and Human Service, in conjunction with other agencies that conduct and fund life sciences research, should develop an education program on the basic principles of risk-based biosafety and biosecurity review" (NRC, 2007).

Education is not just seen as a prerequisite for an effective system of oversight, but also an end goal of some initiatives. For instance, NSABB was also tasked with developing "guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results" (NSABB, 2006a) Yet, many on the Board have stated they do not expect such oversight mechanisms will identify publications as 'of concern' (let alone then subject to some form of restriction) (NSABB, 2006 b). The value of NSABB's *Points to Consider in Assessing the Risks and Benefits of Communicating Research with Dual-use Potential* then is not just its evaluative-review role, but its educational one (NSABB, 2006b). As well, much of the discussion about the utility of codes of conduct has centered on their educational value, rather than their role in compelling certain behaviour (Rappert, 2007a).

While education has been prominent in the past, this is likely to continue. At the 2006 BTWC 6th Review Conference it was agreed that 2008 States Parties will discuss and promote common understanding and effective action on "oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim to prevent misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention" (UN, 2006).

Education Options

Moving from general calls to practical educational instruction requires addressing many questions. For one, who needs to be educated? Principal Investigators (PIs), any senior scientists and staff, administrators, graduate students, and/or undergraduates? Does it matter in what order awareness-raising takes place, that is, what specific subfields of science or roles in the laboratory should be first? What sort of expertise is required to instruct about dual-use issues? What should dual-use education consist of? Is it important to include instruction about general research ethics issues, information on the history of bioweapons programmes, or laboratory security requirements?

Some practical efforts have been undertaken in recent years in the West and elsewhere to enhance the awareness of scientists and others regarding dual-use research (Rappert, 2007 (b)). Three of these are mentioned in this paper to map the diversity of possible responses.

The Life Sciences, Biosecurity and Dual-use Research

Rappert and Dando have conducted more than 100 seminars titled 'The Life Sciences, Biosecurity and Dual-use Research' with practising scientists and students in 11 countries with a breadth of diversity, including the UK, Kenya, Japan, Argentina, and Israel (Rappert et. al, 2007). In part to secure an audience and in part to promote ethical deliberation, these have been held through existing institute research seminar series.

While seeking to inform participants about current life science and security policy debates, the seminars also aim to generate deliberation about how research findings should be communicated, experiments subjected to institutional oversight, and funding for projects determined. Central to the latter aim is promoting interaction *between* colleagues and students. The presenters provide minimal background information prior to the seminars, in order to determine which issues each unique group of attendees deem relevant. Based on past experience with seminars, cases and questions are then introduced into the unfolding discussion to test the limits of and basis for participants' initial statements. That testing is done by finding points of disagreement between participants and then moderating subsequent debate. Two on-line teaching aids have been produced that set to further ethical deliberation (see www.projects.ex.ac.uk/codesofconduct/biosecurityseminar/index.htm).

Case Studies in Dual-use Biological Research

The Federation of American Scientists has produced an online educational resource designed to increase awareness of biosecurity and promote enhanced self-regulation by scientists, titled 'Case Studies in Dual-use Biological Research' (Fas.org/biosecurity/education/dualuse). It examines real-life instances of research intended for civilian applications that generated findings queried for their dual-use implications. Cases include videos with scientists involved with these experiments, in which the scientists elaborate on dual-use aspects of their work and their reasoning for handling them as they did. The module primarily employs these testimonies as the basis for underlining the importance of dual-use issues and encouraging ethical reflection by viewers. General information on dual-use issues and extensive information about the cases are provided through hyperlinks. Throughout, additional written questions are proposed for consideration.

Dual-Use Dilemma in Biological Research

In 2004-5, the Policy, Ethics and Law (PEL) Core of Southeast Regional Center of Excellence for Emerging Infections and Biodefense

(SERCEB) developed an online module to assist those involved with the biological sciences to better understand the dual-use aspects of their research. SERCEB is one of 10 Regional Centers of Excellence funded by the NIH National Institute of Allergy and Infectious Disease to conduct research on bioweapon agents and emerging infectious diseases.

The module consists of five 'chapters' of slides followed by a brief assessment. These chapters include:

1. An introduction to dual-use issues, mainly told through a hypothetical case of a manuscript submission to a journal for publication;
2. A brief account of historical and more contemporary attention to biological weapons with particular emphasis on the implications for contemporary life science research;
3. An overview of the national and international laws governing research that are pertinent to biosecurity;
4. An analysis of the ethical issues associated with dual-use research explored through a more in-depth treatment of the hypothetical journal case; and
5. Consideration of next steps in terms of policy-making (with particular attention to the conclusions of the NRC's report *Biotechnology Research in an Age of Terrorism*) and the hypothetical case study.

By mid-2007, more than four hundred researchers and staff from institutions across the United States and abroad had taken the module. In Spring 2007, 40 semi-structured interviews were undertaken by the authors of this paper to gather feedback on users' experiences, assess general awareness of dual-use issues amongst bioscientists and others at SERCEB institutions, and determine what, if any, outstanding issues related to dual-use concerns may be attended to by revising the module.[6]

[6] Target interviewees were selected from a list of all SERCEB project and programme investigators. Investigators with known awareness of dual-use issues (particularly through interaction with the PEL Core) were excluded, as were all SERCEB Steering Committee members. Potential interviewees were then solicited by email seeking their participation, and/or referral to their laboratory members and colleagues. PIs were asked to identify other laboratory members whom they could recommend. As such, the sample population was initially delimited and then self-selected. In addition to practising scientists, biosafety staff at several main SERCEB institutions were also solicited. Participating interviewees hailed from five main and three affiliate SERCEB institutions. Scientists and technicians interviewed worked in a breadth of disciplines, including bacteriology, virology, vaccine development, immunology and bioengineering.

The interviewees ranged from SERCEB-funded Principal Investigators, members of Principal Investigators laboratories, members of Institutional Biosafety Committees, and biosafety staff. Although a self-selecting and non-representative (relatively) small sample of interviewees that cannot be taken as statistically representative of SERCEB as a whole, the interviews indicated reasons for concern about the extent of prior knowledge about the destructive application of research. For instance:

- Ten (25%) interviewees claimed to be entirely unfamiliar with dual-use issues prior to taking the module. In many cases, interviewees expressed familiarity with certain "select agent" physical security concerns, but not with the term or of the issues posed by the "dual-use" risk. Perhaps most striking was the number of SERCEB PIs (4) that claimed hitherto to have never thought about the nefarious purposes that could be served by their work.
- In terms of module use, of the 40 interviewees, four (4) reported having taking the module prior to being contacted for the assessment project. All four of these individuals were biosafety staff or IBC members. Being personally solicited and asked to participate in an evaluation proved an effective means to motivate individuals to take the module. Previous requests by research directors for individual PIs and their lab members to utilize the module were met by some but not all investigators.
- In four laboratories, lab members interviewed disagreed as to whether or not dual-use issues were relevant to their projects. These include instances in which co-investigators had directly opposing judgments as to whether or not dual-use issues were relevant to their work.[7]

These findings would suggest that further and more extensive research is needed to provide an understanding of scientists' knowledge about the potential for destructive application of their research.

[7] An elaborated and more comprehensive treatment of these interviews is currently under submission.

Closing Remarks

This paper has outlined the place and purpose given to education in policy discussions about dual use issues as well as some of the educational initiatives undertaken to date. These initiatives provide resources and lessons for those wishing to develop educational modules more suitable to their particular situations. Other initiatives of a more preliminary quality might also prove of use. For instance, as a mandated part of the introduction of its 2007 legislation on the physical security of bioagents, the Australian government has been contemplating exactly what sort of education about biosecurity-related issues it should offer its scientists, research administrators and others. The National Defense Medical College of Japan is now considering extending and revising its postgraduate provisions regarding the matter of dual use. Another paper presented as part of this 'Promoting Biosafety and Biosecurity within the Life Sciences' workshop will talk about another initiative in South Africa highly relevant for East Africa.

REFERENCES

Atlas, R., Dando M. 2006. The dual-use dilemma for the life sciences. *Biosecur Bioterror*; 4(3): 276.

British Medical Association. 2002. *Biotechnology, Weapons and Humanity*. London, Harwood Academic Publishers.

Case Studies in Dual Use Biological Research, Available at: http://www.fas.org/biosecurity/education/dualuse/. (Last accessed 14 May 2008).

Centre for Applied Philosophy and Public Ethics. 2006. Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences, Canberra.

Charter – National Science Advisory Board for Biosecurity. 16 March 2006(a): 1. Available at: http://www.biosecurityboard.gov/revised%20NSABB%20charter%20signed%20031606.pdf

Comments made by Paul Kiem as Chair of Communications Work of the National Science Advisory Board for Biosecurity 30 March 2006. See http://www.biosecurityboard.gov/

meetings_archive_033006.asp, at times 4:17:5, 4:20:20, and 4:27-4:28, 4:57.

International Committee of the Red Cross. 2004. Responsibilities of Actors in the Life Sciences to Prevent Hostile Use.

InterAcademy Panel. 2005. IAP Statement on Biosecurity 7 November Trieste: Available at: http://www.interacademies.net/Object.File/Master/5/399/Biosecurity%20St..pdf

McLeish, C., Nightingale, P. 2005. Effective Action to Strengthen the BTWC Regime: The Impact of Dual Use Controls on UK Science. Bradford Briefing Paper May 2005. Available at: http://www.brad.ac.uk/acad/sbtwc/briefing/BP_17_2ndseries.pdf.

National Research Council. 2003 *Biotechnology Research in an Age of Terrorism.* Washington, DC: National Academies Press.

National Research Council. 2006. Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats. Globalization, Biosecurity, and the Future of the Life Sciences Washington, DC

National Research Council. 2007. Committee on a New Government-University Partnership for Science and Security and Committee on Science, Technology and Law. Science and Security in a Post 9/11 World Washington, DC: 12-3.

New Scientist. 2006. 'Dual-use' Biotech - Proceed with Caution. *New Scientist.* 14 October 2006.

NSABB. 2007. Report of the NSABB Working Group on Oversight Framework Development. Bethesda, MD: NSABB.

NSABB. 2006 (a). Charter – National Science Advisory Board for Biosecurity. Available at: http://www.biosecurityboard.gov/revised%20NSABB%20charter%20signed%20031606.pdf

Rappert, B. 2007. *Biotechnology, Security and the Search for Limits*. London: Palgrave

Rappert, B. 2007 (a). Codes of conduct and biological weapons: an in-process assessment. *Biosecurity Bioterrorism*; 5(2): 145-154.

Rappert, B.2007 (b). Education for the life sciences. In *A Web of Prevention*. B. Rappert & C. McLeish (eds.). London: Earthscan.

Rappert B., Chevrier, M., Dando, M. 2007. In-Depth Implementation of the BTWC. Bradford Review Conference Paper No. 18. 2006. Available at: http://www.brad.ac.uk/acad/sbtwc/

Report of Royal Society and Wellcome Trust. 2004. Meeting entitled 'Do No Harm – Reducing the Potential for the Misuse of Life Science Research'.

Royal Society. 2006. Report of the RS-IAP-ICSU International Workshop on Science and Technology Developments Relevant to the Biological and Toxin Weapons Convention. RS Policy Document 38(06), London: Royal Society.

United Nations. 2006. Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. BWC/CONF.VI/6 UN: Geneva.

United Nations. 2002. Annex Report of the Policy Working Group on the United Nations and Terrorism, A/57/273-S/2002/875, 6 August 2002. Available at: http://www.un.dk/doc/A.57.0273_S.2002.875.pdf

University of Exeter: School of Humanities and Social Sciences, The Life Sciences, Biosecurity, and Dual use Research, Available at: http://www.projects.ex.ac.uk/codesofconduct/BiosecuritySeminar/index.htm. (Last accessed May 14 2008)

University of Exeter: School of Humanities and Social Sciences, The Life Sciences, Biosecurity, and Dual use Research., available at: http://www.projects.ex.ac.uk/codesofconduct/BiosecuritySeminar/Education/index.htm (Last accessed May 14 2008)

US National Research Council (NRC) and Institute of Medicine (IOM).2004. Biotechnology Research in an Age of Terrorism, National Academies Press.

Wellcome Trust. 2005. Guidelines on Good Research Practice, available online at: www.portal.smuc.ac.uk/fileadmin/media/public-documents/corporate/research/good-practice pdf.

Wellcome Trust.2008. Managing Risks of Misuse Associated with Grant Funding Activities, available online at www.bbsrc.ac.uk/organisation/policies/position/public_interest/misuse_of_research_joint.pdf, accessed 17 June 2008.

World Medical Association. 2002. Declaration of Washington on Biological Weapons. Washington, DC: WMA.

IMPROVING OVERSIGHT: DEVELOPMENT OF AN EDUCATIONAL MODULE ON DUAL- USE RESEARCH IN SOUTH AFRICA

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Over the past nine years concerns that advances in the life sciences may be used for hostile purposes have increased dramatically. This can partially be attributed to the rapid advances in biology and biotechnology during this period and the consequent increase in the potential that these advances may make biological weapons development easier. But, it is not only advances in the life sciences that has spurred international concern, and increased the perception that the misuse of science presents a threat to societies. When letters containing anthrax spores were sent to high profile individuals in the United States shortly after the World Trade Centre was sabotaged in 2001, it raised alarm bells. Almost every country across the world suddenly had to deal with anthrax hoaxes that tied up forensic laboratories for weeks investigating the nature of powder sent through the post. This served to increase awareness about how biological agents can be used to disrupt society and cause harm.

Outside of the United States, however, the scientific community has remained to a large extent unaware of the discussions and debates that took place (and are ongoing) after 2001 in international and national policy-making forums. These debates and discussions were aimed at finding ways to reduce the risk that benign scientific research could be used by criminals, terrorists or even states to develop biological weapons.

There are a number of factors that complicate efforts to increase controls over scientific research to limit the risk of misuse. Unlike any other weapons, biological weapons have almost no final single-use phase during which the application of technology in research and development is unambiguously intended for weapons purposes. Also, in no other arms category is the active ingredient used both to develop the weapon itself

and to protect the victims from exposure to the effects of that weapon (Zanders, 2004). Many of the research, development and production activities in the areas of defence, protection and prophylaxis against biological weapons are indistinguishable from the ones needed for prohibited weapon development. These characteristics are at the heart of the *dual-use dilemma* that complicates attempts to prevent the misuse of biology. It also underlines the urgency to inform scientists about international and national norms and regulations, the risks of the misuse of science, and their responsibilities as scientists and members of society.

Speak to any microbiologist about controlling or policing the transfer of pathogens as a way of reducing the risk of them landing in the wrong hands and you will quickly be disabused of the notion that control of this nature would be effective. While nuclear materials and chemicals can be monitored and controlled through import and export measures, biological agents occur naturally and can thus be collected by anyone who has sufficient knowledge and expertise. In addition, many microbiologists have stories about the samples of dangerous viruses and bacteria they have flown with as part of their hand luggage without any fear of detection by airport security staff. Far from this being a lesson about how we should be training airport security staff, what it tells us is that, in many respects, individual scientists have to be the first line of defence against the accidental release of pathogens and deliberate misuse. They need to be aware of the concerns about risk, conscious of the dual-use potential of their own work; aware of the national and international conventions and laws, and know where to turn if they encounter an ethical dilemma they are unable to resolve.

Lessons from the South African Experience

In 1998 the South African Truth and Reconciliation Commission revealed details of the Apartheid chemical and biological warfare programme (CBW). The criminal trial of the head of the programme, Dr Wouter Basson, provided additional evidence of the involvement of scientists and health professionals in work that was designed, in many cases, to cause, rather than alleviate, disease and suffering.

It is clear that on an international scale the South African CBW programme was trivial in its scope (this does not refer to its criminal elements) and incompetently managed. But that does not reduce the gravity of the potential it had for doing harm, and there are sufficient indications that the programme was indeed harmful to individuals and quite possibly to communities.

It is inconceivable that senior and experienced scientists employed in the programme would have been unaware, at least in part, of the cynical subversion of science and professional ethical norms that they were furthering. Yet few protested, or left voluntarily, and a number must have joined the programme in the realisation of its true purpose. But this was not a special case. Any country would be able to persuade some of its elite scientists to a secret weapons programme, to defend the interests of the state, particularly when this can be justified in the interest of threatened national security. This we have seen most clearly in the United States since 2001.

The recruitment of scientists to the South African programme was not by coercion; they were quite free to accept or not the attractive offers that were made to them at the time that they joined. Good conditions of service, relatively high salaries, intellectual curiosity, and boredom or frustration with what they had previously been doing were what brought them into the programme. Once in the system, the pressures on them were quite different, to conform and not to challenge it. They were pressures that were understood and generally accepted.

Veterinarians with years of experience in scientific research were willing to approve the ethical standards of experiments on animals that any sense of compassion or concern should have led them to refuse. Organic chemists directed the large-scale production of drugs of addiction for purposes of which they had no inkling. The list is long, albeit incompletely known. With few exceptions, those recruited were known to be sympathetic to the government ideology of the day and were persuaded that there were internal and external threats to the national security that they might play their part in addressing. Undoubtedly, a number

sought opportunities for the advancement of their careers or self-enrichment. And a few would have identified with the very worst of apartheid ideology and welcomed their own special opportunity to serve its implementation. Whatever the original purpose of the programme, the environment of work was such that true scientific contribution was virtually impossible. There was a climate of distrust, threat and, most pervasively, secrecy (Gould and Folb 2000).

After the Truth Commission concluded its work, a meeting was held that brought some of the scientists who were involved in the programme together with members of the scientific and health community to discuss what needed to be done to prevent something like this from happening again. The focus was particularly on what it was that scientists needed to know in order to assess the ethics of their work. It was clear from that meeting that few scientists involved in the programme were aware of the international norm against biological weapons, and few knew where to turn for support and assistance when they did have ethical questions or encountered ethical dilemmas.

During 2004, two workshops were held in South Africa, one in Johannesburg and another in Cape Town. These workshops brought together government representatives, academics, health professionals, scientists and Non-Governmental Organizations (NGOs) to discuss biological weapons issues as they related to South Africa. In both workshops participants noted that there was a very low level of awareness among scientists and science students about the potential for the hostile use of the products of their research, or about the national laws and international agreements banning the use or development of biological weapons. It was agreed that there was a need to create awareness in the scientific community about the norms and laws against the development and use of biological weapons and the responsibilities of scientists to their peers and society to prevent the misuse of science.

During 2007, the Institute for Security Studies held a workshop that brought together academics, practising scientists, government officials and representatives from the Academy of Sciences of South Africa

(ASSAf). The workshop intended to investigate and contribute to the design of an educational module to promote the responsible and ethical use of science in all circumstances, to make scientists aware of the dual-use nature of their work, and how to anticipate and resolve ethical problems and risks, if they arose.

It was agreed that the scope of dual use of science is wide, encompassing chemicals, micro-organisms and biological materials that might be responsible for the natural transmission of disease, for accidentally-induced disease, or that might be deliberately misused. Any approach to countering the misuse of science needs to be both preventive and reactive. Raising awareness amongst the scientific community is one of the preventive measures that could be considered. But awareness-raising of this sort needs the support of the government, academia and scientists in industry.

A number of concepts and issues emerged in the course of the meeting with regard to the development and dissemination of an educational module for scientists. They included that the module should be easily, and freely available to all scientists. That it should contain sufficient information for scientists to understand dual-use issues in relation to their own work. It should provide clear information about the legal responsibilities of scientists and a framework to assist researchers to assess the dual-use potential of their work. It should also provide scientists with a list of professional associations that could assist if a scientist encounters an ethical dilemma.

While such a module should not be seen as the only measure to reduce the risk of the misuse of science for harmful purposes – it is believed that it is an important element of what has become known as the 'web of prevention'. In order for the module to be accepted by the scientific community, collaboration and support from professional associations is essential. In South Africa, the participation of the ASSAf in the process of designing the module was a first step towards getting such support. Indeed, the ASSAf is likely to play a very constructive role in its development and dissemination.

International Support for Awareness Raising

The South African effort has not existed in a vacuum. Internationally there have been a number of calls to create and improve ethics courses for science students. These include (WTWC, 2005):

- A recommendation from The Policy Working Group on the United Nations and Terrorism established by the Secretary General of the United Nations that "…the creation of codes of conduct for scientists, through international and national scientific societies and institutions that teach science or engineering skills related to weapons technologies, should be encouraged".
- A 2002 meeting of all United Nations organizations and agencies that made a recommendation towards "promoting ethics of science education and awareness".
- The Declaration on Science and the Use of Scientific Knowledge made at the World Conference on Science in 1991 stated that: "Each country should establish suitable measures to address the ethics of practice of science and the use of scientific knowledge and its applications."
- In 2003 the International Centre for Genetic Engineering and Biotechnology (ICGEB) held consultations with the US National Academies of Science. The intended result of the consultations was a draft code of conduct for scientists. Building blocks for such a code were presented to a meeting of states parties to the BTWC in 2004. These included the statement that, "Scientists must strive to know, diffuse and teach national and international legislation, regulations and guidelines prohibiting the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons, in particular the Biological Weapons Convention."
- In 2004, the World Health Organization through its Programme for Preparedness for Deliberate Epidemics within the Department for Communicable Diseases Surveillance and Response initiated a process to engage sciences communities,

international and non-governmental organizations, and the private and security sectors about the implications that life science research may have for global health security. The objectives are to raise awareness about these issues in order to protect public health, to safeguard the public health benefits of life science research and to emphasise the public health perspective of such issues in order to promote health equity.

- The International Committee of the Red Cross and the Wellcome Trust too have made statements about the need to encourage the education of scientists from undergraduate level about national and international laws relevant to the prevention of the misuse of science. The Wellcome Trust made a policy statement noting the following: "In order to promote best practice in the conduct of research and maintain public trust, the Trust considers that the international scientific community must take proactive steps to ensure that its members are aware of potential risks and concerns relating to terrorist misuse of research, and of the regulatory and ethical responsibilities they hold" (BTWC, 2005). It added that, "It is essential that the international scientific community engages effectively with society in addressing these risks. The Trust is committed to fostering public engagement on the issues raised by advances in biomedical science, and will consider how it can work in partnership with other organizations to engage the public on issues addressed in this statement" (BTWC, 2005).

It has, therefore, been widely recognised internationally that informed involvement of the scientific community is a vital element of any effort to prevent advances in biotechnology from being use for hostile purposes.

Conclusion

African countries have not, to date, identified biological weapons development and use by states or terrorist groups as a threat. However African states have acknowledged the enormous potential for science to contribute to combating food insecurity and addressing public health

problems. For that reason, increasing the size and scope of the biotechnology efforts on the continent is desirable. However, it is the view of this author that it is also in the interests of Africa to ensure that science is shown to be conducted ethically and that the risk of accidental release of pathogens or the deliberate use of science to cause harm is reduced. One way to do this is by ensuring that biosafety measures are implemented at all facilities. Another is by making sure that scientists are aware of the risks involved with their work and their individual and institutional responsibilities to reduce risk. A broadly implemented on-line educational module for scientists would be a relatively cheap, and easy and effective way to do this.

REFERENCES

Gould and Folb. 2000. "Perverted Science and Twisted Loyalty". *Sunday Independent.* 8 October 2000

Zanders. 2004. Biotechnology Transfers for peaceful purposes: Presentation to the UN Secretary's Advisory Board on Disarmament Matters, Geneva.

Biological Toxins and Weapons Convention. 2005. Online available at: www.disarmament.un.org/WMD/bwc/index.html

6
From the Global to the Local Perspective: Setting Priorities

OVERVIEW

Dual use biotechnology research poses global challenges since legitimate science can create new dangers. The concern about dual-use biotechnology research is a recent phenomenon. There have been efforts to prevent the negative impact of biotechnology, one of which is controlling dangerous pathogens project at the Centre for International and Security Studies at Maryland (CISSM). Out of CISSM's effort has emerged a proposal for protective oversight of dual-use research. This prototype includes national licensing and research facilities, and independent peer review. The features of the CISSM prototype oversight system include: the fact that only the most consequential types of dual-use research are included, it can be readily implemented, it is responsive to the threat in that it covers the pathogens as well as research techniques applied to those pathogens; it is tiered and the level of risk determines the level of oversight. Having a laboratory means that one must have the capacity to do the research, maintain biosafety arrangements and processes, ethical review processes, and build in the dual use issue. The second paper discusses the Uganda national guidelines on how to handle waste or disposal of hazardous chemicals in the agricultural sector, an overview of legislation such as the NEMA Act and the Agricultural Chemicals Act, waste management guidelines that specify empty containers management, waste storage, waste packaging, waste spill management, waste treatment and disposal

methods. The paper discusses restrictions on waste transboundary movement. The paper concludes that it is important to have institutional strengthening and capacity building, sound management of agricultural chemicals, development and implementation of policy and legislative frameworks.

CONTROLLING DANGEROUS PATHOGENS: A PROPOSED INTERNATIONAL BIOSECURITY OVERSIGHT SYSTEM[8]

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Dual-use biotechnology research poses global challenges that cannot be managed effectively either by traditional arms control or by voluntary self-governance alone. Legitimate science can create new dangers if a cutting-edge experiment has unanticipated results, if findings from research done for benign purposes are misused by someone else, or if the line between defensive and offensive biological weapon research becomes blurred in practice or perception. Moreover, the relevant pathogens, equipment, and knowledge are widely distributed in research institutions around the globe (http://cissm.umd.edu/projects/pathogens.php). Efforts to prevent biotechnology from leading to destructive consequences while, at the same time, not hampering beneficial research will require new approaches developed cooperatively by a broad range of stakeholders. One such approach has emerged from the Controlling Dangerous Pathogens Project at the Center for International and Security Studies at Maryland (CISSM).

[8] Portions of this chapter are drawn from Harris, E. D., "Dual-use Biotechnology Research: The Case for Protective Oversight", in Brian Rappert and Caitriona McLeish, eds., *A Web of Prevention: Biological Weapons, Life Sciences and the Governance of Research*, October 2007; Steinbruner, J. D, Harris, E. D., Gallagher, N. and Okutani, S. "Controlling Dangerous Pathogens: A Prototype Protective Oversight System," March 2007, at www.cissm.umd.edu/papers/files/pathogens_project_monograph.pdf; and Steinbruner, J. D. and Harris, E. D., 'Controlling dangerous pathogens,' *Issues in Science and Technology*, Spring 2003, pp. 47-54.

A New Approach

Although dual-use technology has been discussed by arms control and non-proliferation experts for many years, the concern about dual-use biotechnology research is a more recent phenomenon. In February 2001, Australian researchers reported in the *Journal of Virology* that they had inserted an interleukin-4 gene into the mouse pox virus and created a pathogen that was lethal even to some mice that had been vaccinated against the disease.(Jackson et. al., 2001) While the original research had been trying to develop a means of controlling rodent populations, this project and others that followed raised concerns about whether the introduction of IL-4 into other orthopox viruses such as smallpox would have similarly lethal effects.

In the aftermath of the mousepox experiment and amidst controversy over other innovative work, (Harris, 2007) CISSM launched a multi-year effort aimed at trying to address two key questions: What types of dual-use biotechnology research pose the greatest potential danger? How can we manage the risks from such research without impeding scientific progress?

To help answer these questions, CISSM has held numerous workshops in the United States with leading experts from the scientific community, academia, public health and industry. It also has sought to raise awareness on the dual-use issue and to obtain feedback on its ideas through a series of regional workshops that have been held in Hungary for experts from Western and Eastern Europe, in Brazil for experts from Latin American and the Caribbean, in Singapore for experts from the Pacific region, and in Thailand for experts from South Asia and Southeast Asia.

Out of this effort has emerged a detailed proposal for protective oversight of dual-use research that would apply comprehensively to all research institutions conducting relevant research, whether government,

academic or private sector, would rely on mandatory requirements rather than self-governance, and would be global in scope.[9]

This prototype or model oversight arrangement includes two key elements. The first is national licensing or registration of relevant personnel and research facilities.[10] The requirement for some type of personnel licensing or registration would apply to all scientists, students and technical staff proposing to conduct research covered by the oversight system. The purpose would be to ensure that the affected individuals are technically qualified, have undertaken biosecurity training (and thus have been sensitized to the dual-use potential of their work, and educated about both national and international oversight rules) and have nothing in their background (such as a serious biosafety violation) that would make it inappropriate for them to carry out consequential research. The requirement for facility licensing or registration would extend to all facilities where relevant research takes place and would be designed to ensure that such facilities meet existing safety and security standards.

Similar processes are already being used in advanced biology to ensure that certain individuals and facilities meet specified security and safety requirements. For example, under bioterrorism legislation and regulations adopted in the US, background checks are required on any individual having access to certain dangerous pathogens and toxins (designated as 'select agents'), and relevant facilities must be registered.[11] Select agents refer to specific human, plant and animal pathogens whose possession and transfer is regulated by the US government because they can be used for destructive purposes. The law establishing this requirement and associated regulations are Public Law 107–188, 12 June 2002, 42 Code of Federal Regulations 73, 7 Code of Federal Regulations 331, and 9 Code of Federal Regulations 121.

[9] Successive versions of the study have been posted on the CISSM website since 2003. This chapter draws from the March 2007 version cited in note 1 above.

[10] The licensing process and requirements are discussed in more detail in Steinbruner et al, 2007. While the CISSM study focuses on licensing, the author has framed the proposal more broadly to include both licensing and registration.

Various regulations in the US and other countries also require licensing of facilities that produce drugs and other products derived from biotechnology to ensure their safety and efficacy. Outside of biology, there are other examples of licensing requirements for individuals and facilities engaged in activities that could affect substantial numbers of people – such as doctors, or laboratories that work with radioactive materials. A national licensing or registration requirement for individuals and facilities involved in consequential dual-use research would thus be consistent with and build upon these existing requirements.

The second element is independent peer review of relevant research activities prior to their initiation. Any individual interested in conducting research covered by the oversight system would be required to provide information about their proposed project to an independent oversight body for review and approval (Steinbruner et al., 2007).
This is consistent with a recommendation from a US National Academy of Sciences expert group, known as the Fink Committee, which in 2003 called for using local institutional biosafety committees (IBCs) for the initial review of what it deemed dual-use "experiments of concern" (NRC, 2003).

As with national licensing or registration, precedents for independent peer review of consequential research can also be found. Within the US and many other countries, review bodies already exist at the local level for research involving recombinant DNA techniques, human subjects and animals. National- level oversight bodies – such as the Recombinant DNA Advisory Committee (RAC) in the US and the National Biosafety Committee (NBC) in Uganda — also already exist. Internationally, a special committee of the World Health Organization has been given responsibility for reviewing and approving smallpox research at the two designated repositories for the smallpox virus in the US and Russia. A requirement for independent peer review of certain types of dual-use research could be undertaken by similar bodies, thus adding the biosecurity mission to existing biosafety and ethical review processes.

Clearly, any proposals aimed at addressing the threat from dual-use research must balance a number of critical interests. They must protect both the right of scientific investigation *and* the norm against destructive applications of biology. They must provide reassurance both to scientists that they will not be subject to excessive regulation *and* to society that the power of biology is being used appropriately.

To that end, the prototype oversight system developed by CISSM has a number of important features. First, it is narrowly focused in that only the most consequential types of dual-use research are included. Most biomedical and agricultural research would be outside the oversight requirements. Second, it can be readily implemented in that the types of research that must be peer reviewed are clearly defined and presented. Researchers would be able to determine easily whether and, if so, where their proposed work falls within the oversight system and therefore what steps they must take to meet their peer review obligations. This is critical for any oversight system that is mandatory. Third, it is responsive to the threat in that it covers not just specific pathogens, but also the research techniques applied to those pathogens. In so doing, the proposal combines the best of the agent-based controls enacted by the US in 2002 and of the activity-based approach reflected in the Fink Committee's proposed "experiments of concern". Finally, it is based on a tiered design in that the level of risk determines the level of oversight. As discussed below, most research would be reviewed locally at the institutional level, with only a small subset of research considered at a higher level.

At the top of the proposed oversight system there would be a global standard-setting and review body (Steinbruner et al., 2007).This body would be responsible for overseeing and approving activities of extreme concern – research with the most dangerous pathogens or that could result in pathogens significantly more dangerous than those which

[11] Select agents refer to specific human, plant and animal pathogens whose possession and transfer is regulated by the US government because they can be used for destructive purposes. The law establishing this requirement and associated regulations are Public Law 107–188, 12 June 2002, 42 Code of Federal Regulations 73, 7 Code of Federal Regulations 331, and 9 Code of Federal Regulations 121.

currently exist. This would include work with an eradicated agent such as smallpox or the construction of an antibiotic- or vaccine-resistant controlled agent, as was done during the Soviet offensive biological weapons programme.

In addition to overseeing research activities of extreme concern, the global body would also be responsible for defining the research activities subject to oversight under the different categories and establishing standards for review and reporting. It would also develop rules to protect against the misuse of information reported as part of the oversight process. The global body would also help national governments and local review bodies to meet their oversight obligations by, for example, providing software and technical support for a secure data management system and by assisting in achieving international standards for good laboratory practices. This will be particularly important for developing countries, many of which have neither the biosafety rules nor the institutional mechanisms that could provide the basis for dual-use oversight efforts. No existing organization currently fulfils all of these functions. The closest model is WHO, which not only oversees one specific type of highly consequential research, but also has developed international guidelines for laboratory biosafety and biosecurity.

At the next level of the CISSM model there would be a national review body. This body would be analogous to the RAC in the US or the NBC in Uganda. It would be responsible for overseeing activities of moderate concern – research that involves pathogens or toxins already identified as public health threats, especially research that increases the weaponization potential of such agents. This would include research that increases the transmissibility or environmental stability of a controlled agent or that involves production of such an agent in powder or aerosol form, which are the most common means of disseminating biological warfare agents. The national body would also be responsible for overseeing the work of local review bodies, including licensing or registering qualified researchers and facilities, and for interacting with the global body.

At the foundation of the proposed CISSM oversight system there would be a local review body. This committee would be analogous to the review bodies at universities and elsewhere that currently oversee recombinant DNA, human and animal research. It would be responsible for overseeing activities of potential concern – research that increases the potential for otherwise benign pathogens to be used as a weapon or that demonstrates techniques that could have destructive applications. This would include research that increases the virulence of a pathogen or that involves the *de novo* synthesis of a pathogen, as was done in the poliovirus experiment. The vast majority of microbiological research would either fall into this category or not be affected at all.

To ensure equitable treatment of all proposed research projects across countries, common criteria would be needed for the relevant review bodies to use in assessing the potential risks of the work, as well as the possible benefits (Steinbruner et.al., 2007). A comparable risk-benefit assessment process is currently used in the US for reviewing human subject research. As in this review process, the risk-benefit assessment of dual-use biological research should apply to all relevant research, irrespective of whether it is carried out in a government, private sector or academic lab. In addition, the relevant review body should be required to consider certain issues as part of its deliberations and to document the discussion of those issues as well as its overall risk-benefit assessment in its meeting minutes.

Based on a peer review simulation exercise of five hypothetical research projects[12], CISSM has developed a set of proposed dual-use risk-benefit assessment criteria analogous to those used for human subject research. The first two issue areas, which focus on biosafety and the details of the proposed research plan, concern the conduct of the work. The remaining four issue areas relate to the justification for the work and cover public health, biodefence, current necessity and potential impact.

[12]The projects that were peer reviewed are Cloning of MHC I Immunomodulators into Vaccinia Virus; Enhancement of Virulence and Transmissibility of Influenza Virus; Immunosuppression and Immuno-transition in Plague-mouse Model; Manipulation of Temperate Sensitivity in Pospiviroidae; and Exploring New Non-lethal Incapacitation Options.

Similar issues and questions have been suggested by the British Royal Society for assessing dual-use research (Royal Society, 2005).

Conclusion

Scientists, understandably, are concerned about the potential impact of any measures aimed at addressing the dual-use issue. To help respond to this concern, CISSM undertook a survey of scientific journal articles published in the US between 2000 and mid 2005 , to try to determine how much research would have been covered if its proposed oversight system had been in place[13] (Kuhn, 2005). The survey indicated that less than 1 per cent of US publications concerning bacteria, viruses or prions involved research that would have been subject to oversight had an oversight system like CISSM's been in effect. Overall, based on their publications, some 310 US facilities and 2574 US scientists engaged in research activities that fell within the system. Among those that would have been affected, only 12 of the facilities and 185 of the individuals would have been subject to international oversight – a tiny fraction of the American biotechnology research community. Fourteen facilities and 133 individuals would have been subject to national oversight; and 231 facilities involving 2119 individuals would have been subject to local oversight. Fifty-three facilities and 137 individuals would have encountered multiple oversight levels. Those numbers suggest that an oversight system like that developed by CISSM would impinge upon only a very narrow swath of biotechnology research in the US. The impact in other countries would be even more limited.

Until an oversight arrangement like the model developed by CISSM is achieved, other measures of a more limited nature can and should be pursued (Steinbruner et al. 2007). For example, considerable attention has been given by individual scientists and professional scientific

[13] As the working paper makes clear, these are rough estimates only: the author did not screen for all of the categories of research involving non-listed agents because of the overall number of papers and the absence of a suitable search strategy. The figures also do not reflect the broader definition of de novo synthesis used in the more recent version of CISSM's research categories table. At the same time, the author almost certainly included some scientists and facilities that were part of research projects outside of the US simply because they were American or affiliated with an American research facility. Although it is difficult to estimate, these factors could well increase the number of projects subject to local oversight, in particular, by 100 or more.

organizations to the role of scientific codes (Rappert B. 2004). Much of this discussion has focused on ethical codes, which describe personal and professional standards, or codes of conduct that provide guidelines on appropriate behaviour. Serious attention should also be given to codes of practice, which outline enforceable procedures and rules.

But it is not enough to simply have scientific codes, whatever the type. Both students and established scientists should be educated about the details of such codes and the potential for misuse of their work. They should also be informed about relevant laws and regulations governing the conduct of dual-use research and be provided with training to enable them to meet the oversight requirements that are in place. These initiatives could be significantly reinforced if scientific funding agencies and journals required all of those with whom they interact on a professional basis to explicitly consider the dual-use implications of their work, and if all research institutions made this a condition of employment.

Other interim steps could be taken by national governments that would more directly strengthen oversight of dual-use research. The US and other countries that have oversight processes for recombinant DNA research could include specified dual-use research activities in their national regulations and require mandatory adherence by all facilities undertaking such work. These national standards and regulations could then be harmonized among like-minded countries, perhaps on a regional basis. Efforts such as this could be facilitated by the WHO, which has a long history of providing technical information, guidance and assistance to the public, healthcare professionals and policy-makers on the control of dangerous pathogens (www.who.int/csr/delibepidemics/en). In addition to raising awareness about the opportunities and risks of dual-use research, the WHO could take the lead in bringing together the various stakeholder communities to develop technical guidelines for oversight of dual-use research for use by member states.[14]

[14] The development of guidelines for oversight of dual-use research was one of the priority areas identified by a scientific working group convened by the WHO in October 2006. See, World Health Organization, "Scientific Working Group on Life Science Research and Global Health Security, Report of the First Meeting," WHO/CDS/EPR/2007.4, 2007.

There are thus a number of incremental steps that can be pursued by scientists, national governments and international organizations to help prevent biotechnology research from leading either inadvertently or deliberately to the creation of new, more destructive, pathogens. None is sufficient; but all of them can help to lay the foundation for the type of comprehensive, mandatory, internationally harmonized oversight system outlined by CISSM.

REFERENCES

Center for International and Security Studies at Maryland "The Controlling Dangerous Pathogens Project" Available at: http://cissm.umd.edu/projects/pathogens.php

Harris, Elisa D., 2007. Dual Use Biotechnology Research: The Case for Protective Oversight in Brian Rappert and Caitriona McLeish, eds. A Web of Prevention: Biological Weapons, Life Sciences and the Governance of Research.

Jackson, R. J., Ramsay, A. J., Christensen, C. D., Beaton, S., Hall, D. F., and Ramshaw, I. A. 2001. Expression of mouse interleukin-4 by a recombinant Ectromelia virus suppresses Cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. *Journal of Virology*, February, pp. 1205–1210.

Kuhn, J. H. 2005. Qualitative and Quantitative Assessment of the Dangerous Activities Categories Defined by the CISSM Controlling Dangerous Pathogens Project. CISSM Working Paper, December.

National Research Council. 2003. Biotechnology Research in an Age of Terrorism. Washington, DC.

Steinbruner, J. D, Harris, E. D., Gallagher, N. and Okutani, S. 2007. Controlling Dangerous Pathogens: A Prototype Protective Oversight System. Available at www.cissm.umd.edu/papers/files/pathogens_project_monograph.pdf;

Rappert, B. 2004. Towards a Life Sciences Code: Countering the Threat from Biological Weapons. Bradford Briefing Paper, 2nd series, no 13.

Royal Society. 2005. The Roles of Codes of Conduct in Preventing the Misuse of Scientific Research. Royal Society Policy Document, Available at: www.royalsoc.ac.uk/displaypagedoc.asp?id=13648.
WHO Epidemic and Pandemic Alert Response: Preparedness for

Deliberate Epidemics, Available at: www.who.int/csr/delibepidemics/en/
.
WHO, 2007. Scientific Working Group on Life Science Research and Global Health Security, Report of the First Meeting," WHO/CDS/EPR/2007.4, 2007, Available at: http://www.who.int/csr/resources/publications/deliberate/WHO_CDS_EPR_2007_4/en/.

NATIONAL GUIDELINES ON HOW TO HANDLE WASTE OR DISPOSAL OF HAZARDOUS CHEMICALS IN THE AGRICULTURAL SECTOR IN UGANDA

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Uganda is predominantly an agricultural economy with the agricultural sector contributing 38% of the gross domestic product (GDP), employing 80% of the population in the rural areas and is a main source of foreign exchange. Government has introduced several programmes to transform its agriculture. Notable among them is the Plan for Modernization of Agriculture (PMA). PMA aims to achieve a transformation of the currently predominant subsistence farming into a dynamic and profitable commercial agriculture where farmers produce for the market. With this policy move, increased usage of agricultural chemicals by farmers is expected to rise to reduce the risk of losses in crop production caused by nutrient deficiency, harmful organisms and weeds.

In the country, agricultural chemicals are split into fertilizers and pesticides with the annual imports about of 141,657,020kg of fertilizers

and 4,414,705.41/Kg pesticides (Import Record MAAIF, 2007 a). In terms of product category, fungicides dominate import volume (38.7%), followed by herbicides (36.5%), insecticides (23.8%) and others (1%). Once the agricultural chemical has been used, the farmer is left with an empty used pesticide packaging/container. Typical empty packs in use are the rigid metal drum, plastic containers made of HD-PE and PET, paper packaging materials and PET plastic containers in volumes ranges from 1, 5, 20, 50 to 200-L and the total quantities is estimated at over 3 million used empty containers/year dotted around in the urban and rural areas in the country.

The growth in trade during the past years has raised both public and official concerns about the potential risks posed by these chemicals and the resultant wastes that include the obsolete chemicals, empty used pesticide packaging/container, contaminated packaging and equipment, discarded protective clothing and waste resulting from dealing with spills and leaks of pesticides, other materials (such as treated seed, protective gears contaminated with pesticides or left over spray solutions and rinse water).

Overview of the Legislations

The National Environment Act, Cap. 153

The National Environment Act, Cap. 153 established the National Environment Management Authority (NEMA) as the principal agency in Uganda for the coordination, monitoring and supervision of all environmental matters (NEMA, 1995). Under Section 53 of this Act, NEMA is mandated to make regulations and guidelines for the classification and management of hazardous wastes. NEMA released the National Environment (Waste Management) Regulations 1999. Section 56 of this Act, provide the mandate for the lead agency to issue guidelines and prescribe measures for the management of toxic and hazardous chemicals. In the case of agricultural chemicals, the Agricultural Chemicals Board under Ministry of Agriculture, Animal Industry and Fisheries, established under the Agricultural Chemicals (Control) Act, 2006, is the lead agency (MAAIF, 2006).

The Agricultural Chemicals (Control) Act, 2006

The Agricultural Chemicals (Control) Act, 2006 repealed the Control of Agricultural Chemicals Statute, 1989. It an Act to control and regulate the manufacture, storage, distribution and trade in, use, importation and exportation of agricultural chemicals and for other related matters. Under Section 18 of this Act, the Minister in consultation with the Agricultural Chemicals Board is mandated to make regulations and guidelines for the disposal and safe destruction of agricultural chemicals wastes.

- The Agricultural Chemicals (Registration and Control) Regulations, 1993 Section 34 applies to the disposal of agricultural chemicals and its related wastes (MAAIF, 1993)
- Draft Agricultural Chemicals Waste Regulations 2007 (Pending) (MAAIF, 2007b) will replace the current "Agricultural Chemicals (Registration and Control) Regulations, 1993, Section 34" will bring into force the controls specified under the Agricultural Chemicals (Control) Act, 2006. These regulations apply to all categories of agricultural chemical waste; the storage and disposal of waste and their movement into and out of Uganda; and all waste disposal facilities, landfills, sanitary fills and incinerators;
- Draft guidelines outline procedures for the classification, segregation, safe packaging (containment), labeling, storage, transport and disposal of agricultural chemicals and related wastes (including concentrates, ready-to-use formulations and pesticide solutions), contaminated materials and equipment and pesticide packaging. They are intended to assist authorities and practitioners, as well as other people involved (whether directly or indirectly), in determining an appropriate waste management strategy. Top of Form

Waste Management Guidelines

All generators of agricultural chemical wastes are responsible for the safe management and disposal of these wastes in an environmental sound manner that minimises risk to the community and worker involved in its management. Each generating farm/distributor should have a comprehensive waste management plan as part of an overall environmental management strategy with a designated individual responsible for its implementation. In developing a waste management plan, the guideline requires facility to:

- Take account of the need for ensuring a high standard of worker safety;
- Consider the minimisation of waste through a purchasing policy that avoid over-ordering or over-supply arising from purchasing systems that are not aware of actual pesticide needs in the field.
- Examine the procedures for waste segregation (separation at source) and keeping them apart during handling, accumulation, interim storage and transport.
- Establish procedures and staff training programmes for effective waste management that ensures compliance with relevant guidelines and regulations
- Develop appropriate risk management strategies that document both contingency plans and emergency procedures, including those for spills containment.

Empty Container Management

Empty agricultural chemical containers shall be properly triple-rinsed and cleaned to avoid polluting the environment and posing potential threat to public health, animal and wildlife. Rinsing of containers shall take place on the farm itself immediately after emptying them and then added to the spray tank and sprayed on crop.
Containers which are not suitable for rinsing (for example, paper sacks and cardboard cartons) and those containing products which are either ready-to-use or not applied as a solution (gassing tablets/powders such

as aluminium, magnesium or zinc phosphides), are normally emptied completely but not rinsed. These will have the phrase 'Empty container completely and dispose of safely' on the label. One should handle and store these empty containers as if they still contain the pesticide, and should dispose of them through a licensed waste-disposal contractor.

Waste Storage

Storage facilities for waste should be suitably sited, lockable and appropriately sign-posted. They must be kept secure at all times. The establishments are responsible for providing designated storage areas with adequate lighting, ventilation and provisions for the containment of spills within the storage area, Waste security and restriction of access to authorised persons, and storage area designed so that routine cleaning and post-spill decontamination are easy to undertake.

For small wastes, the requirement for a designated storage area may be achieved by the use of a suitable rigid walled container for the storage of empty cleaned container that has been punctured, shredded or crushed to make it un-usable.

Waste Packaging

The establishment shall ensure that hazardous agricultural chemical wastes are packaged, labelled, and transported in conformity with generally accepted and recognized international rules and standards in the field of packaging, labelling and transport, and that due account is taken of relevant internationally recognized practices.

No person shall pack an agricultural chemical waste or toxic substance in a container which will react chemically or physically with the substance it is to contain; and is not of sufficient strength for handling and transportation to prevent the escape of agricultural chemical waste. No person shall re-pack, decant or dispense any agricultural chemical waste into food or beverage containers. No person shall load for transportation any packages which are damaged, severely corroded or which show evidence of leakage.

Waste Spill Management

Establishments can be held responsible for related waste spills that may occur both on-site and during transportation. Personnel who may be involved in spills management must receive training in emergency procedures and handling requirements. Spill kits containing all items necessary to clean up spills should be available in an easy accessible area. Typical contents include absorbent (saw-dust, sand, etc), buckets, shovel, gloves, overalls, face mask/shield, torch. Washing from spills should not be disposed of via the storm water drainage system.

Waste Treatment and Disposal Methods

There are a range of methods available to treat and dispose of agricultural chemicals and related wastes. The methods used depend on specific factors applicable to the legislation and environmental aspects affecting the community. Any treatment option selected should render the waste unrecognizable, achieve a significant volume reduction, result in residues being suitable for approved landfill disposal without harmful leaching to the environment, meet occupational health and safety standards and result in minimum levels of hazardous or toxic by-product

Agricultural chemicals and related waste treatment and disposal methods currently approved include:

- Product re-use if laboratory analysis established that the agricultural chemical past guaranteed shelf-life could still be used;
- Diluted pesticide waste applied to the treated or untreated crop or area within the terms of the product approval;
- Burning;
- Landfill – site must be physically contained (engineered) to controlled movement of leachate. Public access to the point of disposal should be restricted. Soil or other waste may be used for immediate covering of the waste. Land filling of liquid wastes is not permitted;

- Incineration - carried out in a multiple-chambered incinerator that has mechanisms for closely monitoring and controlling the combustion parameters. Where incineration is used, the emission standards and ash disposal should be addressed;
- Recycling of materials for other applications, or energy recovery in cement kilns or power plant or re-use as pesticide containers;
- The best way to deal with the disposal of treated seed is to minimize amount of treated seeds that need to be discarded. Seed Handlers should take a "cradle to grave" approach in the area of identifying and tracking of seed treatment materials.

Agricultural chemicals and related wastes SHOULD NOT be disposed of through indiscriminate dumping and open-air incineration, domestic incinerator, fire box, incineration in 200-litre drums or unapproved incinerators with single chamber where combustion is usually incomplete and involves uncontrolled temperature.

In accordance with the "polluter pays" principle, the cost of disposing of waste is an undertaking giving rise to the waste. The costly nature of waste disposal leads to accumulation of waste given that institutions would be avoiding the cost.

Restrictions on Waste Transboundary Movement

Export for Final Disposal and for Recovery

No Export of Hazardous Waste is allowed except for destruction purposes in accordance with the Basel Convention and in accordance with the National Environment (Waste Management) Regulations 1999.

Import for Final Disposal and for Recovery

Regarding the transboundary movement of hazardous waste, the import is prohibited. However, persons desiring to import or export any wastes may apply for a license by completing a movement document, which conforms to the Basel Convention requirements. NEMA is required to

notify other States through which the waste will transit in order to seek their informed consent.
In order to ensure tight control/monitoring of possible illegal hazardous waste imports into the country, only a few points have been designated as entry ports.

Conclusion

- Institutional strengthening and capacity building of MAAIF and other ministry concerned with wastes handling to remedy the problem and want/need assistance to construct one at the newly constructed National Referral Pesticide Laboratory at Namalere;
- The sound management of agricultural chemicals and its related wastes is essential if we are to achieve sustainable development, including the eradication of poverty and disease, the improvement of human health and the environment;
- Developing and implementing policy and legislative frameworks that foster integrated and comprehensive approach to chemicals and waste management and that addresses all stages of the product life cycle;
- Carrying out a survey on inventory of used empty packaging/ containers of agricultural chemicals. The initial focus is on empty containers available at the Estates. Areas to be addressed include;
    - Inventory type, sizes and quantities
    - A centralised holding store
    - Cleaning
    - Selection of best recycling use.

REFERENCES

MAAIF. 1993. The Agricultural Chemicals (Registration and Control) Regulations, 1993.
MAAIF. 2006. The Agricultural Chemicals (Control) Act, 2006.
MAAIF. 2007 a. Import Record 2007.

MAAIF 2007 b. Draft Agricultural Chemicals Control (Disposal) Regulations, 2007.
NEMA. 1995. The National Environment Act, Cap. 153.

APPENDIX A
AGENDA

UGANDA NATIONAL ACADEMY OF SCIENCES (UNAS)

Promoting Biosafety and Biosecurity within the Life Sciences: An International Workshop in East Africa

March 11-12, 2008

Hotel Africana
Kampala, Uganda

Meeting Objectives:

To inform African scientists and policy-makers on issues related to the inadvertent or deliberate spread of disease stemming from life science research; and to provide a platform that brings international experts on biosafety and biosecurity in direct contact with local scientists, academy members and policy-makers in order to initiate dialogue regarding policy responses and practical institutional measures stemming from presentations by the experts.

DAY 1, MARCH 11 2008

Chair:	Patrick Rubaihayo, Makerere University
8:00 – 9:00	Registration of Participants
9:00 – 9:05	Welcome and Opening Remarks Paul E Mugambi, Uganda National Academy of Sciences
9:05 – 9:20	Keynote Address: Edward Katongole Mbidde, Director Uganda Virus Research Institute

Session I: Overview and Introduction (9:30am-11:00am)

Session Objective: To introduce the concept of biosafety and biosecurity from a global to a local perspective specifically focusing on how this information relates to and is important in Africa

Moderator:	Dominic Makawiti, Kenya National Academy of Sciences
9:20 – 9:40	The Spectrum of Risks to Global Health and Security Ottorino Cosivi, World Health Organization
9:40 – 9:50	Discussion
9:50 – 10:10	Biotechnology and biorisk in Africa Ben Steyn, South African Military Health Services
10:10 – 10:20	Discussion
10:20 – 10:40	Biosecurity: The Web of Prevention Malcolm Dando, University of Bradford, UK
10:40 – 10:50	Discussion

10:50 - 11:10 BREAK – 20 min

Session IIa: Biosafety (11:30-1:15)

Session Objective: To provide background information that will inform scientists and policy-makers when developing institutional and national policies that will help prevent accidental outbreaks from dangerous pathogens

Moderator:	Idris Kikula, Tanzania Academy of Arts and Sciences
11:10 – 11:25	Biosafety and Biosecurity in microbiological laboratories (15 min) Ronald Atlas, Former President of the American Society for Microbiology
11:25 – 11:40	Risk Assessment: Biosafety Training, Oversight, Resources and Reporting (15 min)Jennifer Gaudioso, Sandia National Laboratories

11:40 – 11:55 Developing National Biosafety Systems
Theresa Sengooba, International Food Policy Research Institute

11:55 – 12:30 Panel Discussion

12:30 – 13:30 LUNCH BREAK

Session IIb: Biosafety and Biotechnology in Uganda (11:30-1:15)

Session Objective: To provide an understanding and bring participants up-to-date on issues of Biosafety and Biotechnology in Uganda

Moderator: Elly Sabiiti, Faculty of Agriculture, Makerere University

13:30 – 13:45: Role of National Biosafety Committees in Biotechnology Development Opuda-Asibo, Makerere University

13:45 – 13:55 Discussions

13:55 – 14:10 Analysis of the Biosafety System in Uganda: Regulatory framework, policies and procedures
Charles Mugoya, Association for Strengthening Agricultural Research in East and Central Africa

14:10 -14:20 Discussions

Session III: Biosecurity (2:15- 3:45)

Session Objective: To facilitate discussion around the "web of prevention" as it applies to all international and national efforts to try and prevent deliberate outbreaks from exposure to dangerous pathogens by using such means as oversight of experiments, codes of conduct and appropriate levels of laboratory biosecurity measures

Moderator: Rachael Chikwamba,
14:20– 14: 35 Developing National Biosecurity Systems
Heidi Mahy, Pacific Northwest National Laboratory

14:35 – 14:50	Engaging Scientists in Biosecurity: An African Perspective' (15 min) Eucharia Kenya, Kenyatta University
14:50- 15:05	The potential of mycotoxins as chemical warfare agents Gordon Shephard
15:05 – 15:35	Panel Discussion

15:35 – 15:55 BREAK – 20 min

Session IV: Building a Coalition (3:50- 5:05)

Session Objective: To show how scientists and policy-makers can work together with academies in developing sound policies in biosafety and biosecurity

Moderator:	George W. Lubega, Makerere University
15:55 – 16:10	ASSAF Standing Committee on Biosecurity (15 min) Simon Rambau, Academy of Science South Africa
16:10 – 16:20	Discussion
16:20 – 16:35	Improving Oversight: Development of an Educational module on dual- use research in the West Brian Rappert, University of Exeter, UK
16:35 – 16:50	Improving Oversight: Development of an Educational module on dual- use research in South Africa Chandre Gould, ISS
16:50—17:20	Discussion

18:00 Welcome Reception

DAY 2, MARCH 12, 2008

Chair:	Patrick Rubaihayo, Makerere University
8:30 – 9:00	Registration

Session V: From the Global to the Local Perspective: Setting Priorities (9:00-13:00)

Session Objective: To build capacity within research institutions to devise and undertake laboratory biosafety and biosecurity oversight review procedures

Moderator:	Theresa Sengooba, International Food Policy Research Institute
09:00 – 09:15	Laboratory biosafety, laboratory biosecurity and biosecurity of life science
	Ottorino Cosivi, WHO
09:15- 09:30	A Proposed International Biosecurity Oversight System Elisa Harris, University of Maryland
9:30 – 9:45	National laboratory guidelines on how to handle waste or disposal of hazardous chemicals
	Michael Odong, Ministry of Agriculture, Animal Industries and Fisheries, Uganda
9:45 - 10:15:	Panel Discussion

10:15 - 10:35 BREAK

Moderator:	Gabriel Ogunmola, Nigeria Academy of Sciences
10:35 – 10:45	Summary of Sessions I-V and Introduction to Roundtable Discussions
	Ronald Atlas, Former President of the American Society for Microbiology
10:45 – 11:45	Roundtable Discussions on biosafety and biosecurity Facilitator: Malcolm Dando

	Biosafety/Biosecurity Scientist Roundtable: Reactions to presentations (30 min) Jo Husbands Brian Rappert Chandre Gould **Kenya** Wallace D. Bulimo Hamadi Bwoga Francis J. Mulaa **Uganda** Joseph Mukiibi Andrew Kiggundu Facilitator: Charles Mugoya Biosecurity/Biosafety Policy Maker Roundtable: Setting national priorities (40 min) **Kenya** Jacob Ole Miaron Franklin Bett Patrick Ayiecho Olweny **Tanzania** Jacob Mtabaji Esther Mwaikambo William Sabaya **South Africa** Rachael Chikambwa Kelebohile Lekoape **Uganda** Richard Tushemereirwe Gordon Katende Ssematiko Henry Richard Kimera
11:45 – 12:10	Large group discussion (30 min)
12:10 – 12:15	Closing Remarks Patrick Rubaihayo, Chair
12:15 - 13:15	**LUNCH BREAK AND ADJOURN OPEN MEETING**

Session VI: (Closed Session) Media Workshop- By Invitation (14:00 – 17:00)

APPENDIX B
SPEAKERS, MODERATORS, AND ROUNDTABLE DISCUSSANTS BIOGRAPHIES

SPEAKER BIOS

EDWARD KATONGOLE MBIDDE is the Director Uganda Virus Research Institute and the former head of Mulago Hospital Uganda National Cancer Institute of Makerere University and a practising Medical Oncologist. Dr. Mbidde obtained his MBCHB degree from Makerere Medical School in 1972 and specialized in Internal Medicine obtaining qualification. He specialised further in medical oncology in the UK. His responsibilities include teaching both the undergraduate students as well as residents in internal medicine at Makerere Medical School. He has conducted research locally and internationally. Dr. Mbidde has served on many committees locally and internationally and has presented at many international scientific meetings.

OTTORINO COSIVI is the is leading the project for Preparedness for Deliberate Epidemics, based in the Biorisk Reduction for Dangerous Pathogens team, Department of Epidemic and Pandemic Alert Response (EPR) at WHO headquarters, Geneva. Since 1997, Dr Cosivi has been working on the public health implications of the deliberate use of biological agents to cause harm. He was the secretary of the international group of experts that drafted the 2nd edition of the WHO publication 'Public health response to biological and chemical weapons:

WHO Guidance' (2004). The main areas of his current activities include: tools for national health preparedness, networks and standards for disease risks such as anthrax and brucellosis, and implications of life science research for global health security. Dr Cosivi has been representing WHO at various meetings of the Biological Weapons Convention and other relevant networks. He started his WHO career in 1993 working on surveillance and control of diseases common to humans and animals. Dr Cosivi qualified in Veterinary Medicine at Parma University, Italy, and has a post-graduate degree in Tropical Veterinary Medicine from Edinburgh University, Scotland. He has worked with industry, non-governmental organizations, academic institutions and as a practitioner in various countries.

BEN STEYN has been Chemical and Biological Defence Advisor to Surgeon General since 1993.Since 1992 he has been a member of the South African Delegation to negotiations and meetings of States Parties of the Biological Weapons Convention. He is also Chairperson of two technical subcommittees of the Council for the Non-Proliferation of Weapons of Mass Destruction, providing the Council with technical advice on non-proliferation issues regarding chemical and biological weapons. He acts as advisor to various Government Departments such as the South African Police Service and Department of National Health and Disaster Management. He has contributed to two books and is co-author of another. He is the author of a number of articles on various aspects of Chemical and Biological Defence and Non-Proliferation. He has delivered numerous presentations and lectures over the world on various aspects of Chemical and Biological Defence and Non-Proliferation.

MALCOLM DANDO is a professor of International Security at the University of Bradford and has continued to co-direct the Department's project on strengthening the Biological and Toxin Weapons Convention (BTWC). With Professor Graham Pearson, he edited a further 16 Briefing Papers (Nos 12-27) and a new series of Evaluation Papers (Nos 1-11) and assisted with the presentation of these papers to the

delegations of the States Parties at the negotiations in Geneva. Under a grant from the Foreign and Commonwealth Office, he assisted in the production of the first three in a new series of International Security Information Service (ISIS) Briefing Papers on 'Preventing Deliberate Disease'. All of this material, along with the official documentation from the Ad Hoc Group of States Parties negotiating the Verification Protocol to the BTWC, is available on the Department's website. Malcolm also assisted in the organisation of four NATO Advanced Research Workshops (ARWs) on technical issues connected with the negotiations and was a key speaker at them all. These ARWs were held in Prague (two), Moscow and Bucharest. With Professor Pearson, he wrote the NATO Guide to Best Practice for organizing such workshops. In January 1999, the British Medical Association issued a report, written by Malcolm, on the dangers of new biological weapons, particularly those which might be used to target specific ethnic groups (*Biotechnology, Weapons and Humanity*, Harwood Academic Press, London). This issue was discussed by him in more technical detail in the 1999 *SIPRI Yearbook* of the Stockholm International Peace Research Institute. The evolution of offensive biological warfare programmes over the last century was detailed in an article in Defense Analysis and the efforts of the international community to develop legal means of control over these appalling weapons was set out in a long paper for the *Finnish Yearbook of International Law* (1999). Malcolm has just completed the book, *New Biological Weapons: Threat, Proliferation and Control*, for Lynne Rienner Publishers. This deals with the little-discussed problem of future toxin and bioregulator weapons and how such misuse of science might best be prevented. He has been an invited expert to meetings of the Pugwash scientists' organization (which received the Nobel Peace Prize in 1995), the International Committee of the Red Cross in Geneva, the Chemical and Biological Arms Control Institute in Washington D.C., the British Federation of Women Graduates, and a meeting of environmental campaigners (against genetically modified organisms) in Blue Mountain, New York State. Malcolm has been a member of the validation group for the University of Southampton project on 'Nuclear Weapons and Security:

Alternative Strategies for Nuclear Policies', and he has chaired the last two annual international conferences on 'Non-Lethal Weapons' organized by Jane's Information Services in London. He was the expert advisor for the Equinox TV programme on the 'Deadly Code' and did the follow-up, on-line, question and answer session for Channel 4. Other popular presentations included contributions to the *Sunday Times* series, 'Chronicle of the Future'. Malcolm recently completed a study for the Ministry of Defence on 'The impact of the use of chemical or biological weapons and agents on the ability of British forces to carry out military operations in the period 2000-2020'. He has also lectured on 'The proliferation of biological weapons' to the Advanced Command and Staff Course at the Joint Services Command and Staff College, Bracknell. Professor Dando's work has mainly been supported by grants from the Joseph Rowntree Charitable Trust, the Airey Neave Trust and the United States Institute of Peace. He was elected a Fellow of the Institute of Biology in March 1999.

RONALD M. ATLAS is Graduate Dean, Professor of Biology and Public Health, and Co-director of the Center for Health Hazards Preparedness at the University of Louisville. He received his BS degree from the State University at Stony Brook, his MS and PhD degrees from Rutgers the State University, and a DSc (honoris causa) from the University of Guelph. He was a postdoctoral fellow at the Jet Propulsion Laboratory where he worked on Mars Life Detection. He is chair of NASA's Planetary Protection Subcommittee, co-chair of the American Society for Microbiology (ASM) Task Force on Biodefense. He previously served as President of ASM, was a member of the NIH Recombinant Advisory committee, was on the Board of Governors of the Council of Graduate Schools (CGS), and was a member of the DHS Homeland Security Science and Technology Advisory Committee. His early research focused on oil spills and he discovered bioremediation as part of his doctoral studies. Later he turned to the molecular detection of pathogens in the environment which forms the basis for biosensors to detect biothreat agents. He is author of nearly 300 manuscripts and 20 books. He is a fellow in the American Academy of Microbiology

and has received the ASM Award for Applied and Environmental Microbiology, the ASM Founders Award, and the Edmund Youde Lectureship Award in Hong Kong. He regularly advises the US government on policy issues related to the deterrence of bioterrorism.

JENNIFER GAUDIOSO, is a Principal Member of the Technical Staff in the International Biological Threat Reduction Program at Sandia National Laboratories (SNL), focusing on the safety and security of high risk pathogens and toxins in laboratories and in transportation systems. She specializes in risk assessment, analysis of biological agents, and transport security issues. She is an expert on counter-bioterrorism and biological weapons non-proliferation. She also has broad laboratory biosafety experience and training. She has written multiple publications in these fields, including as a co-author on the *CRC Press Laboratory Biosecurity Handbook*. She serves on SNL's Institutional Biosafety Committee and is an active member of the American Biological Safety Association. She has participated in security assessments at US government bioscience facilities, and has contributed to the development of international biosecurity guidelines. She has conducted biosecurity projects for the US Departments of State, Homeland Security, Energy, Health and Human Services, and Agriculture. She has also worked extensively on laboratory biosafety and biosecurity issues internationally. In recent years, she has organized the Asia Conference on Laboratory Biosafety and Biosecurity and many international workshops on laboratory biosafety and biosecurity. Over the past few years, she has consulted on these topics at basic and high containment bioscience laboratories in over a dozen countries. She earned her PhD at Cornell University.

THERESA SENGOOBA is the Regional Coordinator for the Programme for Biosafety Systems (Eastern Africa). Previously, she joined the National Agricultural Research Organisation (NARO) of Uganda in 1993, later becoming Director of Research and Plant Pathologist at Namulonge Agricultural and Animal Research Institute (NAARI). She holds BSc and MSc (Agriculture) degrees of Makerere

University and a PhD from Sokoine University of Agriculture (Tanzania). Before joining NARO, she was PRO/Plant Pathologist, Ministry of Agriculture Animal Industry and Fisheries. She also worked as Programme Leader, National Bean Programme for 6 years. She is a member of: ACSS, Applied Biology based in the UK and Uganda Professional Women's Association (UPWA). She is interested in community-based education and development activities.

JOHN OPUDA-ASIBO has been Professor of Epidemiology, Public Health and Preventive Veterinary Medicine at Makerere University since1997. He has been chairman of the National Biosafety Committee of Uganda with experience in examining quality assurance of genetically modified organisms and biosecurity systems since 2005, Director Posta Uganda and Chairman Audit Committee. He previously worked as Director of the School of Graduate Studies, Makerere University (1999 to 2003) and Head of Department of Veterinary Public Health and Preventive Veterinary Medicine, Makerere University (1984 to 1999). He has over 31 years of University lecturing and teaching of a wide range of courses, advising Graduate students (MSc and Ph.D.); Research projects formulation, evaluation and financial awarding; Development of audio-visual aids for training; Curriculum Development in both Undergraduate and Postgraduate studies; Demographic Surveillance and Site Establishment; Research Management and Coordination; and Resource mobilization. He is an external examiner at several universities, a Student of Biosafety since 1978 as a graduate student in the USA, he is a member (1996 – 2011) and Chairman (2005 – 2011) of the Uganda National Biosafety Committee, and is part of several Expert panels He has been a chairman on various boards and has published widely.

CHARLES F. MUGOYA is a Ugandan. He holds a BSc in Botany and Zoology from Makerere University, Uganda, MSc in Agricultural Entomology from University of Nairobi, Kenya and PhD Applied Entomology from Rivers State University of Science and Technology, Port Harcourt, Nigeria. After his PhD in 1991, he worked as a resident

scientist for ICIPE in Zambia up to 1995, and joined the National Council of Science and Technology in Uganda from 1996-2004, where he worked as Associate Executive Secretary and Regional Coordinator for the BIOEARN Programme, a position he held for 6 years. He was also appointed in 1998 as Project Coordinator of the UNEP/GEF Project for the development Uganda National Biosafety Framework and in 2002 he coordinated a second phase on the implementation of the Uganda National Biosafety Framework. Currently, he is Programme Manager, Agrobiodiversity and Biotechnology Programme of ASARECA. He can be contacted at: P.O. Box 765, Entebbe, Uganda, Phone/fax: +256 41 322126, Cell: +256 772 966662, Email: c.mugoya@asareca.org or mugoyac@yahoo.com

HEIDI MAHY is a scientist with Pacific Northwest National Laboratory and an associate of the Pacific Northwest Center for Global Security. After graduating from Cornell University with degrees in French and Biology she worked for a private pharmaceutical corporation, focusing on developing new anti-cancer drugs and immunology research. She received her Master's degrees in International Studies and Business Administration from the University of Washington, Seattle, Washington, and joined Pacific Northwest National Laboratory. Currently, Ms. Mahy provides technical assistance to the Department of Energy (DOE) and the U.S. Interagency Working Group (IWG) on matters related to the Biological and Toxin Weapons Convention (BTWC), including areas such as disease surveillance, codes of conduct, emerging technologies, and DOE biotechnology assets. She is also project manager for a DOE project on outreach and education in the life sciences, focusing on dual-use awareness and development of a biosecurity culture in the U.S. DOE National Laboratory complex. She supports the Pacific Northwest Center for Global Security in various areas, including work on biosecurity. Recent work includes international outreach and engagement on biosecurity topics, convening a regional workshop on improving disease surveillance capabilities and communication, and developing Commodity Identification Training (CIT) material for the DOE/NNSA/NA-242 INECP program.

EUCHARIA KENYA Studied Zoology, Medical Parasitology, and Applied Entomology for her BSc, MSc, and PhD respectively. She is currently the Acting Dean, School of Pure and Applied Sciences, Kenyatta University and Senior Lecturer Department. of Biochemistry and Biotechnology, Kenyatta University, Nairobi, Kenya. Her research interests include: molecular characterization of insects and parasites, study of host-parasite and vector-parasite interactions, epidemiology of parasitic disease (human and animal) – public health implications, emerging and re-emerging diseases in the urban environment (particularly malaria and HIV/AIDS) and risk management of genetically engineered crops – environmental impact. She belongs to various professional societies such as International Network of Women Scientists and Engineers, Biochemical Society of Kenya, Entomological Society of Kenya among others. Dr. Kenya also has over twenty publications.

GORDON SHEPHARD has a PhD degree in Chemistry from the University of Cape Town, South Africa. Currently he is the sub-programme leader for analytical chemistry in the PROMEC Unit (Programme on Mycotoxins and Experimental Carcinogenesis) of the South African Medical Research Council. Dr Shephard is currently the Topic Advisor for aflatoxin methods and General Referee for mycotoxins for AOAC International. He has served as consultant and advisor for both the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) and was vice-chair of the 56th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). He serves on the editorial board of a number of journals, including *Applied and Environmental Microbiology and Food Additives and Contaminants* and is a section editor of the new *World Mycotoxin Journal*. He has served on the scientific committee for the past three International IUPAC Symposia on Mycotoxins and Phycotoxins and on the advisory committee of the World Mycotoxin Forum. Dr Shephard has published widely in the mycotoxin field and has over 100 publications on mycotoxin-related issues.

SIMON RAMBAU has been an International Liaison Officer at the Academy of Science of South Africa (ASSAf) since January 2007. His main responsibility is to coordinate all ASSAf international activities such as to maintain the bilateral engagements with other international science academies and to ensure that ASSAf Members participate within the multilateral organizations such as IAMP, IAP, NASAC, AAS, TWAS and SADC in order to advance scientific work in Africa. Other responsibilities include serving as an Executive Secretary for Committee of Heads of Organisation for Research and Technology, Coordinating the establishment of ASSAf Biosecurity Committee and facilitating the establishment of a South African Chapter of the World Academy of Young Scientists in Africa. Previously worked as a Capacity Building Technical Advisor for the South African Revenue Service (SARS) and served as a South African representative in the East and Southern Africa Regional Capacity Building for World Customs Organisation (WCO) based in Kenya from 2005 – 2006. Have been extensively involved in the reconstruction of the Democratic Republic of Congo (DRC) during the build-up to the 2006 elections and participated in numerous presidential commissions to DRC. Participated in the diagnostic project for Lesotho Revenue Authority and developed a capacity building programme in order to implement the finding of the diagnostic mission. Served as a Training Project Manager during SARS transformation in 2004 – 2005 and facilitated development programmes to revitalize and maximize the potential of SARS employees through accredited programmes such as 7 Habits of Highly Effective people and other leadership development programmes.

"I am currently a third-year doctorate student in education specializing in curriculum development from University of Pretoria. The focus of my doctoral thesis is to examine the contribution of disaster education in enhancing communities' resilience to disasters. I completed a Masters degree in Education at University of Pretoria in 2004 specialising in Maximizing Human Potential in Education and Training, BEd (Honours) with specialisation in Guidance and Counselling, BA degree from University of Pretoria majoring in History, Education and Communication as a sub-major."

BRIAN RAPPERT is an Associate Professor of Science, Technology & Public Affairs in the Department of Sociology and Philosophy at the University of Exeter (UK). Currently he is funded by the Alfred P. Sloan Foundation to promote engagement with dual-use research issues within the international life science community. His most recent books include a study of how humanitarian limits are placed on the conduct war (titled *Controlling the Weapons of War: Politics, Persuasion, and the Prohibition of Inhumanity*- 2006), an edited book examination (w/C. McLeish, University of Sussex) of the components for preventing the destructive use of life science research (titled *A Web of Prevention*) and an investigation of dual-use educational seminars undertaken with Malcolm Dando (titled *Biotechnology, Security and the Search for Limits* - 2007). For more information about his education work see: http://www.projects.ex.ac.uk/codesofconduct/BiosecuritySeminar/index.htm
For more information about his research in general see: http://www.people.ex.ac.uk/br201/

CHANDRE GOULD is a senior researcher at the Institute for Security Studies. Between 1996 and 1999 she was in investigator and evidence analyst for the Truth and Reconciliation Commission, where she was involved in the investigation of Project Coast - the chemical and biological weapons programme of the Apartheid government. After 1999 she continued researching Project Coast and co-authored a monograph published by the United Nations Institute for Disarmament Research, and several papers and articles. She also co-authored a commercially published book about the trial of Dr Wouter Basson in 2002. Since 2002 she has been involved in national and international efforts to strengthen the norm against biological weapons and has written extensively on the issue. In 2006 she obtained her PhD from Rhodes University. She is currently completing a two-year research project on human trafficking while continuing with her work to raise awareness about biosecurity-related issues.

ELISA HARRIS is a Senior Research Scholar at the Center for International and Security Studies at Maryland (CISSM). From 1993 to 2001, she was Director for Non-proliferation and Export Controls on the National Security Council staff, where she had primary responsibility for coordinating U.S. policy on chemical, biological and missile proliferation issues. Ms. Harris has held a number of research positions, including in the Foreign Policy Studies programme at the Brookings Institution, the Royal United Services Institute for Defence Studies in London and the Center for Science and International Affairs at Harvard University. She is a former SSRC-MacArthur Foundation Fellow in International Peace and Security Studies and staff consultant to the Committee on Foreign Affairs, U.S. House of Representatives. Ms. Harris is the author of numerous publications on chemical and biological weapons issues and has testified frequently before the U.S. Congress. She has an A.B. in Government from Georgetown University and an M.Phil in International Relations from Oxford University.

MICHAEL ODONG is a Principal Agricultural Inspector at the Ministry of Agriculture, Animal Industry and Fisheries, Uganda. He is also the in-charge Agricultural Chemicals Registration and Control. He studied at the University of New South Wales, Sydney, Australia for a Master of Applied Science Degree in Food Technology with strong background in Quality Assurance and interest in Microbiology. He has had vast training in Biosafety monitoring of Genetically Modified Organisms and other products of modern biotechnology training programme, strengthening national food safety systems through enhanced participation in the CODEX process, International Standards for Phytosanitary Measures and Phytosanitary Systems Evaluation training, Risk Assessment Training among others.

MODERATOR BIOS

DOMINIC WERE MAKAWITI is a Professor of Biochemistry and Deputy Vice-Chancellor (Academic Affairs) he holds HSC, S1 (KSTC), BSc Hons (Nairobi), PhD (London), MIBiol, MKNAS. He is a Kenyan, born in 1955; married; can speak and write Luo, English, Kiswahili, French (little). Prof. Makawiti joined University of Nairobi as Lecturer in 1985 rising to full Professor of Biochemistry in 1998. Served as Chairman of the Department of Biochemistry for 10 years (1992-2002); he was Associate Dean, Pre-Clinical Departments for 7 years (1996-2002); Dean, School of Medicine for two terms, 4 years (2002-2006); Acted on several occasions as Principal of the College of Biological and Physical Sciences and the College of Health Sciences and is currently the Deputy Vice-Chancellor (Academic Affairs), Maseno University, a position he has held since February 2007. Prof. Makawiti has had several appointments such as Secretary, Natural Products Research Network for Eastern and Central Africa-Kenya, (1986-1992); Secretary, Biochemical Society of Kenya (1989-1992); Chairman, Biochemical Society of Kenya (1992-1998); President, Federation of African Societies of Biochemistry and Molecular Biology (1996-2000); Treasurer, Kenya National Academy of Sciences (2000-present); Chairman, Board of Directors, Nyumbani (2003-present). Chairman, Board of Governors, Nyabondo High School (2004-present); Member, Board of Governors, Kenya Science Teachers College (1998-2007); Member, Board of Directors, University of Nairobi Enterprises and Services (UNES, 2002-2007); Member, University of Nairobi Council (2004-2007); Member, International Council for Science (ICSU) Regional Committee for Africa (2005-present). He also was awarded the Head of State Commendation (HSC) by His Excellency, the President of the Republic of Kenya. Prof Makawiti has vast experience in teaching Biochemistry. He has been an external examiner to a vast number of universities. His research interests include but are not limited to: Biochemical Endocrinology with emphasis on (a) Steroid hormones, their metabolites, techniques of identification and quantification, and

use in prediction and detection of ovulation and prediction of parturition. (b) Natural products of plant origin involved in fertility regulation. (c) Effect of trypanosomosis on the host endocrine function. (d) Nutritional bioenergetics. He has over 30 peer reviewed and published scientific articles**.**

IDRIS KIKULA is the Vice Chancellor of the University of Dodoma, Tanzania, and a professor at the same University. He is also a member of the Tanzania Academy of Arts and Sciences.

ELLY SABIITI is a Professor of Crop Science and until recently, Dean of the Faculty of Agriculture, Makerere University, Uganda. His research interests have included fire ecology of savannas and the evaluation and integration of pastures in crop-livestock production systems. He has participated in professional missions to many countries in Africa and internationally and has published more than 32 scientific papers. He received his bachelor and masters degrees in agriculture from Makerere University and a PhD in range ecology from the University of New Brunswick, Canada. He was recently appointed research professor for the Academy of Sciences of Developing countries (TWAS). He is married with six children.

RACHAEL CHIKAMBWA is the Research Group Leader of the Plant Biotechnology group of the CSIR Biosciences. She holds an adjunct position as a senior lecturer in the Department of Botany and the Forestry and Agricultural Research Institute (FABI), University of Pretoria. She holds a Masters degree in Plant Breeding and Genetics from the University of Queensland in Australia and a Doctorate in Genetics from Iowa State University the USA. Her research focused on molecular breeding and expression of foreign genes in transgenic plants. She worked as a research associate at the Department of Biology in the School of Life Sciences at Arizona State University, USA, studying optimization of expression and assembly of multi-subunit proteins in plants. Dr Chikwamba worked in programmes on the application of biotechnology in resource-poor small-scale agriculture and has

participated in many regional initiatives on the development of policies and priorities on biosafety and agricultural biotechnology research in Southern Africa in the early nineties. Her interest in crop improvement research is the use of biotechnology tools to alleviate biotic and abiotic stresses in crop plants. Her research in applied plant biology also involves the production of novel molecules in transgenic plants. Rachel is currently involved in many collaboratively research initiatives funded by the Royal Society, the EU Sixth Framework, Bill and Melinda Gates Foundation and the Rockefeller Foundation. Dr Chikwamba is a Fellow of CSIR Biosciences, and an Honorary Research Fellow at St Georges, University of London, and a member of the Academy of Science of South Africa. Dr Chikwamba is a recipient of several awards, including fellowships from the Rockefeller Foundation, the Australian International Agency for Development Bureau (AIDAB) and a Research Excellency Award from Iowa State University. Currently, Dr Chikwamba is recipient of Research of Grants from the Rockefeller Foundation, The NRF/Royal Society and Department of Science and Technology. She has authored several articles in peer reviewed internationally renowned scientific journals and several book chapters. She has refereed grants for local and international funding bodies and has made several invited presentations internationally.

GEORGE W LUBEGA is a Senior Lecturer in the Faculty of Veterinary Medicine, Makerere University.

THERESA SENGOOBA (SEE SPEAKERS BIOS).

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PROF. ESTHER MWAIKAMBO is a highly accomplished Professor of Medicine, with considerable experience in scientific fields, in policy matters, and in University administration and management affairs. Previously she also served as Vice Chancellor; and at present she is Vice President, and Acting President of the Tanzania Academy of Sciences (TAAS).

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RICHARD TUSHEMEREIRWE has been the Assistant Private Secretary, Science and Technology, in the president's office since 2004. He has been an Educationist sine 1995 where he lectured at Kyambogo University in the department of biological sciences.

HON. GORDON KATENDE SSEMATIKO is a Member of Parliament in Uganda representing Mityana North Constituency. He is the Vice Chairman of the Science and Technology Committee of Parliament. He is a member of the Information Communication Technology Committee of Parliament. He holds a Masters Degree in Pharmacy and a Masters Degree in Business Administration. Before joining politics, he worked as the chief Pharmacist at Mulago Hospital, the National Referral Hospital for Uganda.

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JO HUSBANDS is a Senior Project Director at the National Academy of Sciences (NAS) and an Adjunct Professor at the Edmund A. Walsh School of Foreign Service, Georgetown University. She has also served as the Director of the Development, Security, and Cooperation Division in the NAS Office of International Affairs. Previously, she was Director of the Academy's Project on Democratization and a Senior Research Associate for its Committee on International Conflict and Cooperation. Before joining the NAS, Dr. Husbands was Deputy Director of the Committee for National Security, a Washington, DC-based non-governmental organization. She serves on the editorial boards of *International Studies Quarterly, International Politics*, and *International Studies Perspective*. Dr. Husbands has published widely on the topics of arms controls, arms transfers, weapons proliferation, and international negotiations. She is also a member of the advisory board of Women in International Security.

WALLACE DIMBUSON BULIMO is currently the virology chief, laboratory director and principal investigator of the Influenza Surveillance in Kenya programme under the United States Department of Defense's Global Emerging Infections Surveillance and Response System (GEIS) Department. He received his Bachelors and Masters degrees in 1993 and 1997 respectively from the Department of Biochemistry, University of Nairobi. He obtained his PhD in Molecular Virology from the University of Hertfordshire, UK, in 1999. Upon obtaining the doctorate, Dr Bulimo joined the Institute for Animal Health, UK, as a postdoctoral research fellow in the division of Immunopathology. He returned to

Kenya in 2000 and joined ICIPE before moving to the University of Nairobi in 2002 as a lecturer in the Department of Biochemistry. He served in this capacity until May 2006.Dr Bulimo has been involved in a number of biosafety and biosecurity committees in Kenya. In 2005, he served as the biosafety consultant on the University of Nairobi Institutional Biosafety Board that approved the phase I/II Clinical Trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine boosted by a multiclade HIV-1 recombinant Adenovirus-5 vector in HIV uninfected adult volunteers in East Africa. This trial is being undertaken in Kenya under the Kenya Aids Vaccine Initiative (KAVI). In 2006, Dr Bulimo and Professor Mulaa conceptualized and conducted the institute-wide biosafety training course offered to the entire staff of the International Livestock Research Institute (ILRI). He is currently a member of the Kenyan joint taskforce for the Avian/ pandemic Influenza preparedness. Dr Bulimo is a member of the Biochemical Society of Kenya (BSK), American Society for Microbiology and the International Society for Influenza and other Respiratory Virus Diseases (ISIRV).

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JOSEPH K MUKIIBI joined the National Agricultural Research Organisation (NARO) of Uganda in 1993, later becoming its Director General (thus head of the Secretariat, guiding and supervising research and related programmes of constituent institutes. He holds a BSc (Botany and Chemistry), University College of London and a PhD (Mycology and Plant Pathology) University of St Andrews, Scotland, UK. Before joining NARO, he was Secretary for Research, Ministry of Agriculture, Animal Industry and Fisheries (MAAIF). He also worked as a researcher on coffee, Lecturer in Crop Science and Head

of the Departments of Forestry and Crop Science, and Dean of the Faculty of Agriculture and Forestry, Makerere University (Uganda). Joseph Mukiibi became Professor of Plant Science in 1977, was Visiting Professor at Nairobi University (Kenya) and at Sokoine University of Agriculture (Tanzania), and a Fulbright Fellow at the University of California, Davis, USA. He is a member of: International Institute of Tropical Agriculture (IITA), Centro Internationale de Agricultura Tropicale (CIAT), Special Programme for African Agricultural Research, Washington DC (SPAAR), Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), National Environment Management Authority (NEMA), Forum for Agricultural Research in Africa (FARA), and New York Academy. Prof Mukiibi has now left NARO and currently works as a Consultant. He is also the National Chairperson of the Democratic Party (DP) of Uganda.

WILBERFORCE TUSHEMEREIRWE works with Kawanda Agricultural Research Institute under the National Agricultural Research Centre.

APPENDIX C
ACRONYMS

AIA	Advance Informed Agreement
ASM	American Society of Microbiology
ASSAF	Academy of Science of South Africa
BC	Biological and Chemical
BTWC	Biological Trade and Weapons Convention
BWC	Biological Weapons Convention
CBD	Convention on Biological Diversity
CDC	Centers for Disease Control
CISSM	Center for International and Security Studies of Maryland
COMESA	Common Markets for East and Southern Africa
CONSENT	Consumer Education Trust
DNA	Deoxyribonucleic Acid
DOE	Department of Energy
DRC	Democratic Republic of Congo
EAC	East African Community
ECOWAS	Economic Community of West African States
FAO	Food and Agricultural Organisation
FFP	Food, Feed, Processing
FMD	Foot and Mouth Diseases
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GE	Genetic Engineering
GEF	Genetically Engineered Foods
GM	Genetic Modification

GMOs	Genetically Modified Organisms
HIV	Human Immunodeficiency Virus
IAP	Inter Academy Panel
IARC	International Agency of Research on Cancer
IBC	Institutional Biosafety Committees
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICRC	International Committee of the Red Cross
ICSU	International Council for Science
IOM	Institute of Medicine
IPPC	International Plant Protection Convention
IPR	Intellectual Property Rights
LMOs	Living Modified Organisms
MAAIF	Ministry of Agriculture, Animal Industries and Fisheries
NBC	National Biosafety Committee
NEMA	National Environment Management Committee
NIH	National Institute of Health
NRC	National Research Council
NSABB	National Science Advisory Board for Biosecurity
OHSAS	Occupational Health and Safety Management
OIE	Office International des Epizooties (World Organisation for Animal Health)
PEL	Policy Ethics and Law
PMA	Plan for Modernization of Agriculture
RAC	Recombinant DNA Advisory Committee
RNA	Ribonucleic Acid
SADC	Southern Africa Development Community
SERCEB	Southeast Regional Center of Excellence for Emerging Infections and Biodefence
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade Agreement
UN	United Nations
UNCST	Uganda National Council for Science and Technology

UNEP	United Nations Environment Programme
UNEP-GEF	United Nations Environment Programme- Global Environment Facility
UNSCR	United Nations Security Council Resolutions
USG	United States Government
WDCM	World Data Center for Micro-organisms
WFCC	World Federation of Culture Collections
WHO	World Health Organisation
WMD	Weapons of Mass Destruction
WTO	World Trade Organization
WTWC	World Toxic Weapons Convention

APPENDIX D
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