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By Chair, Hon. Rachel Njiru on 22/11/2016
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ELEVENTH PARLIAMENT - FOURTH SESSION - 2016

THE NATIONAL ASSEMBLY

THE DEPARTMENTAL COMMITTEE ON HEALTH
REPORT ON
THE RATIFICATION OF THE AGREEMENT BETWEEN THE GOVERNMENT OF
THE REPUBLIC OF KENYA AND THE GOVERNMENT OF THE UNITED STATES OF
AMERICA CONCERNING CO-OPERATION IN THREAT REDUCTION BIOLOGICAL
ENGAGEMENT PROGRAMS

DIRECTORATE OF COMMITTEE SERVICES,
CLERK'S CHAMBERS,
PARLIAMENT BUILDINGS,
NAIROBI.

NOVEMBER, 2016

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DEFINITION OF TERMS

BWC	-	Biological and Toxins Weapons Convention
CVL	-	Central Veterinary Laboratories
DOD	-	Department of Defense
GOK	-	Government of Kenya
KEMRI	-	Kenya Medical Research Institute
UNSCR	-	United Nations Security Council Resolution
USA	-	United States of America

CHAIR'S FOREWORD

On 19th July, 2016, the Leader of the Majority Party in the National Assembly tabled in the House a Cabinet Memorandum on The ratification of the Agreement between the Government of the Republic of Kenya and the Government of the United States of America concerning Cooperation in threat reduction biological engagement programs pursuant to section 8 of the Treaty Making and Ratification Act, 2012.

The Agreement was subsequently committed to the Departmental Committee on Health for consideration and to report back to the House. Once ratified, the agreement shall become part of the laws of Kenya as provided for in Article 2(6) of the Constitution that *"any treaty or convention ratified by Kenya shall form part of the law of Kenya under this Constitution"*.

The Committee is thankful to the Office of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its Sittings.

On behalf of the Committee, it is therefore my pleasant duty and privilege, to lay this report on The ratification of the agreement between the Government of the Republic of Kenya and the Government of the United States of America concerning cooperation in threat reduction biological engagement programs and seek approval of the National Assembly for ratification of the Agreement Pursuant to Section 8(4) of the Treaty Making and Ratification Act, 2012 and Standing Order 199.

Signed.....



Date.....

17 / 11 / 2016

THE HON. DR. RACHAEL NYAMAI, M.P.
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

EXECUTIVE SUMMARY

The purpose of this report was to consider the ratification of the Agreement between the Government of the Republic of Kenya and the Government of the United States of America concerning cooperation in threat reduction biological engagement programs

In considering the agreement, the Committee held a total of five (5) sittings. The Committee received a comprehensive brief on the matter from Legal Office and the Parliamentary Budget office.

Pursuant to Article 118 (1) (b) of the Constitution on public participation and section 8(3) of the Treaty Making and Ratification Act of 2012, the Committee placed advertisements in two local dailies, on Thursday, 4th August, 2016, (Annex 3) requesting for submissions of memoranda on the subject matter. The Committee however did not receive any submissions from the public.

As part of public participation, the Committee invited the Cabinet Secretaries for Health; National Treasury; Foreign affairs and International Trade; Defense and Interior & Coordination of National Government. The Cabinet Secretary for Health as a key stakeholder in the matter attended the sitting while the Principal Secretary for Defense, represented the Cabinet Secretary. The Attorney General's Office and National Treasury sent representatives to the meeting. On 14th September 2016, the Committee also held a consultative meeting with the Ministry of Health for further clarification on the emerging issues by the Committee. The Minutes of these sittings are appended to this report.

The report recommends that the National Assembly approves the ratification of the agreement.

1.0 PREFACE

1.1 Mandate of the Committee

The Committee on Health is one of the Departmental Committees of the National Assembly established under Standing Order 216 with the following terms of reference;

- i) investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned Ministries and departments;
- ii) study the programme and policy objectives of Ministries and Departments and the effectiveness of the implementation;
- iii) study and review all legislation referred to it;
- iv) study, assess and analyse the relative success of the Ministries and Departments as measured by the results obtained as compared with their stated objectives;
- v) **investigate and inquire into all matters relating to the assigned Ministries and Departments as they may deem necessary, and as may be referred to it by the House;**
- vi) vet and report on all appointments where the Constitution or any law requires the National Assembly to approve, except those under Standing Order 204 (Committee on Appointments) ; and
- vii) make reports and recommendations to the House as often as possible, including recommendation of proposed legislation.

The Committee is mandated to consider matters related to health, medical care and Health Insurance

Oversight

In executing its mandate, the Committee oversees the Ministry of Health, and the Semi-Autonomous Government Agencies and regulatory bodies under the Ministry.

1.2 Members of the Committee

The Hon. Dr. Rachel Nyamai, M.P.	Chairperson
The Hon. Dr. Robert Pukose, MP	Vice Chairperson
The Hon. Alfred Agoi, M.P.	
The Hon. Alfred Sambu, M.P.	
The Hon. David Karithi, M.P.	
The Hon. Dr. Dahir Duale Mohamed, M.P.	
The Hon. Dr. David Eseli, CBS, M.P.	
The Hon. Dr. Enoch W. Kibunguchy, M.P.	
The Hon. Dr. James Murgor, M.P.	
The Hon. Dr. James Nyikal, M.P.	
The Hon. Dr. James O. Gesami, M.P.	
The Hon. Dr. Naomi Shaban, M.P.	
The Hon. Dr. Patrick Musimba, M.P.	
The Hon. Dr. Stephen Wachira, M.P.	
The Hon. Dr. Susan Musyoka, M.P.	
The Hon. Eng. Stephen Mule, M.P.	
The Hon. Fred Outa, M.P.	
The Hon. Hassan Aden Osman, M.P.	
The Hon. James Gakuya, M.P.	
The Hon. John Nyaga Muchiri, M.P., HSC	
The Hon. Jared Opiyo, M.P., M.P.	
The Hon. Kamande Mwangi, M.P.	
The Hon. Leonard Sang, M.P.	
The Hon. Robert Mbui, M.P.	
The Hon. Michael Onyura, M.P.	
The Hon. Mwinga Gunga, M.P.	
The Hon. Paul Koinange, MP	
The Hon. Raphael Milkau Otaalo, M.P.	
The Hon. Zipporah Jesang Kering, M.P.	

1.3 Committee Secretariat

Clerk Assistant III	Ms. Esther Nginyo
Clerk Assistant III	Mr. Dennis Mogare
Clerk Assistant III	Ms. Ruth Mwihaki
Legal Counsel I	Ms. Marlene Ayiro
Senior Research & Policy Analyst	Ms. Marale Sande
Fiscal Analyst I	Mr. Joash Kosiba

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1.4 List of Recommendations

The Committee recommends that:

1. The National Assembly approves the ratification of the agreement as it is in the interest of the Country in line with the World Health Organization - International Health Regulations in addressing biological threats and pathogens.
2. The Multi-agency Implementing Committee (envisioned in Article VII- sub-article 3) be established immediately after the ratification of the Agreement to facilitate the effective implementation of the agreement as envisage in Article II.
3. The Agencies involved in the implementation should develop the requisite capacity to be able to effectively implement this agreement.
4. All laws on waiver of taxes be taken into consideration when implementing the agreement.
5. The Implementing Review Committee be constituted and should develop a mechanism for reporting back to Parliament on the status of implementation of the agreement.
6. The Ministry of Health together with the other state agencies charged with handling of pathogens should develop the standard national list of pathogens.
7. The Ministry of Health should provide a list of specific goods and services under this agreement to be exempt from taxes, duties, levies.
8. The State Law Office should fast track the draft Biosecurity Bill to be passed by Parliament so as to provide a legal framework on which to anchor issues of bio safety and bio security.

2.0 INTRODUCTION

2.1 The Ratification of the Agreement Between the Government of the Republic of Kenya and the Government of the United States of America Concerning Cooperation in Threat Reduction Biological Engagement Programs.

The Agreement between the Government of the Republic of Kenya and the Government of the United States of America concerning cooperation in threat reduction biological engagement programs was signed by Mr. James Macharia, the then Cabinet Secretary of Health on behalf of the Government of Kenya and Ambassador Robert F. Godec, Ambassador of the United States of America to Kenya on 24th July 2015.

The Agreement was subsequently transmitted to the Cabinet vide a Cabinet Memorandum jointly signed by Dr. Cleopa Mailu, Cabinet Secretary for Health on 29th February 2016 and Prof. Githu Muigai, the Attorney General on 1st March 2016. The Cabinet Memo sought the Cabinet approval for the ratification of the agreement. The Cabinet and Parliament's approval processes of such international Agreements are anchored in the Treaty Making and Ratification Act No. 45 of 2012

The Cabinet approval for the ratification of the Agreement was granted during a Cabinet meeting held on 1st April, 2016 in line with the requirements of Section 8(1) of the Treaty Making and Ratification Act, 2012.

2.2 Purpose of the Agreement

The Agreement desires to establish a cooperative program to facilitate mutually beneficial efforts to reduce biological threats of common concern between the two countries. The purpose of the cooperative program is to facilitate efforts to reduce the threats from naturally occurring diseases, biological attacks, or unintentional release of biological pathogens and toxins, and the risks posed by non-state actors of bioterrorism.

The Government of the United States of America agreed to provide to the Government of Kenya, assistance in support of efforts to identify; detect; predict; monitor; control; safeguard against; reduce; eliminate; prevent the proliferation of; ensure safe storage

and transport of; enhance reporting of; improve mechanisms for response to; and strengthen research, training, and education related to biologic threats.

The projects envisaged in the program shall consist of mutually agreed projects related to potential biological threats, including naturally occurring diseases, biological attacks, or unintentional releases of biological pathogens or toxins, and biological weapons-related pathogens and toxins, materials, processes, and knowledge.

2.3 The Objectives of the Agreement

According to the Cabinet Memo, the objectives of the Agreement are two-fold:

- (i) Enhance the Government of Kenya's capability to identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens.
- (ii) Enhance the Government of Kenya's capability to rapidly and accurately survey, detect, diagnose and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements.

The application of the Agreement does not envisage amendment(s) to the Constitution of Kenya.

2.4 Scope of the Cooperation

Article II of the Agreement outlines the scope of cooperation in the agreement which covers wide range of issues related to reducing threat from naturally occurring diseases, biological attacks, or unintentional releases of biological pathogens and toxins, and the risks posed by non-state actors of bioterrorism. Areas of cooperation under the agreement may include but are not limited to:

- i) Comprehensive, sustainable, and legally embedded national programs for biosafety and biosecurity;
- ii) Supporting the implementation of an effective nationwide laboratory system within Kenya;

- iii) Implementation of a functioning surveillance system within Kenya, capable of identifying and responding to potential events of concern to health security from biological pathogens and toxins;
- iv) Implementation of policies and practices to minimize the spillover and spread of emerging diseases;
- v) Supporting collaborative research programs in bio surveillance, biosecurity, and biosafety.

The scope of the agreement covers a variety of subject matter ranging from human health; animal health; nationwide laboratory systems; biosafety and biosecurity; and disease surveillance among others. The implementation of the activities under the scope of the Agreement will greatly enhance Kenya's capability to identify and rapidly detect, diagnose and report biological terrorism and outbreaks of pathogens and diseases of security concern

2.5 Executive Agents and Implementers of the Agreement

Article III of the Agreement designates the Ministry of Health, in collaboration with the Ministry of Defence and the Ministry of Interior and Coordination of National Government as the Executive Agent for the Government of Kenya. However each party through its executive agents may delegate rights and responsibilities under the Agreement to other agencies, departments, or units of its government or to other entities as deemed appropriate by written notification to the other party.

2.6 Planned Activities under the Agreement

According to the Cabinet Memo, the activities under the Agreement will be mutually agreed upon by the two governments based on the scope of the cooperation. The present activities planned under the agreement are:-

- i) Infrastructural upgrades and constructions at Isiolo and Kajiado Level IV Hospitals laboratories;
- ii) Construction of Sample Management Facility and Other Infrastructural upgrades at Central Veterinary Laboratories (CVL), State Department of Livestock, and the Kenya Medical Research Institute (KEMRI);

- iii) Infrastructural upgrades at the Kenya Veterinary Vaccine Production Institute (KVVPI), Embakasi Nairobi.

There are more activities and projects that are envisaged based on the Agreement's scope of cooperation.

2.7 Monitoring Framework and Timelines of the Agreement

The Agreement does not specify the duration within which the Agreement shall remain in force. There are also no timelines within which the various projects under the Agreement will be undertaken.

The Agreement provides in Article VIII (3) that Parties to the Agreement shall establish a committee to monitor the implementation of the Agreement. However, the structure and composition of the monitoring committee is not provided. It is also not clear as to which Party will meet the administrative expenses including the cost of secretariat to the Committee.

2.8 Financial Implication

According to the Cabinet Memo, the implementation of this Agreement envisages no direct financial implication to Kenya since the Government of the United States of America will provide as appropriate and at no cost to the Government of Kenya assistance in support to the implementation of the Agreement.

However Article V of the Agreement provides that Kenya will be required to accord tax exemptions to the personnel of the US government in the Country engaged in the implementation of the Agreement and the goods and services used in the implementation of the Agreement.

It is the considered opinion of the Parliamentary Budget Office that tax exemptions and waivers by the Government of Kenya will lead to a direct loss of revenue by the government hence a direct financial implication in the form of tax expenditure.

3.0 SUMMARY OUTLINE OF THE AGREEMENT

The cooperation in threat reduction biological engagement programs agreement

Contains (twelve) Articles as follows:

Preamble	Preamble	It sets out the reasons and aspirations for which the agreement is made particularly the need to initiate a cooperative program to develop, strengthen and maintain core national Public health Capacities to prevent, protect against and control the spread of disease
Parties	Parties	(1) Kenya; (2) United States of America
Article I	Purpose	Provides for the Purpose of the Agreement which is to facilitate efforts to reduce the threat from naturally occurring diseases, biological attacks, or unintentional release of biological pathogens and toxins, and the risks posed by non-state actors of bioterrorism
Article II	Scope of Cooperation	Provides that the parties shall pursue cooperation in pursuing the goal of reducing the threat from naturally occurring diseases, biological attacks, or unintentional reuses of biological pathogens and toxins, and the risks posed by non-state actors of bioterrorism. Areas of cooperation under this Agreement may include but are not limited to: a. Implementation of a comprehensive, sustainable, and legally embedded national program for biosafety and biosecurity; b. Enhancement of the Government of the Republic of Kenya's capability to identify, consolidate, and secure collections of biological pathogens and toxins of security concern in order to prevent the sale, theft, diversion, or accidental release of biological pathogens and toxins; c. Enhancement of the Government of the Republic of Kenya's

		<p>capability to rapidly and accurately survey, detect, diagnose, investigate alleged misuse of biological pathogens and toxins, and report biological terrorism and outbreaks from biological pathogens and toxins of security concern in accordance with international reporting requirements;</p> <p>d. Implementation of a functioning surveillance system within Kenya, capable of identifying and responding to potential events of concern to health security from biological pathogens and toxins;</p> <p>e. Implementation of policies and practices to minimize the spillover and spread, of emerging diseases;</p> <p>f. Supporting the implementation of an effective nationwide laboratory system within Kenya, capable of safe and accurate detection, identification, and characterization of biological pathogens and toxins of security concern, including both known and novel threats, that leverages regional resources and is commensurate with available technological capacities;</p> <p>g. Supporting collaborative research programs in bio-surveillance, biosecurity, and biosafety;</p> <p>h. Supporting human resource development programs in biosafety and biosecurity: and</p> <p>i. Supporting training and awareness creation on biosafety and biosecurity issues</p>
Article III	Executive Agents and implementing Agreements	<p>Provides for each party to designate an executive Agent responsible for the coordination of cooperative activities under the agreement.</p> <p>The United States Department of Defense is designated as the executive agent for the Government of the United States of America, unless the Government of the United States of America otherwise notifies the Government of the Republic of</p>

		Kenya. The Ministry of Health, in collaboration with the Ministry of Defense and the Ministry of Interior and Coordination of National Government, shall be the executive agent for the Government of the Republic of Kenya unless the Government of the Republic of Kenya otherwise notifies the Government of the United States of America
Article IV	Costs	Provides for the expenditures by the Government of the United States of America pursuant to this Agreement, including associated expenses and transportation costs.
Article V	Taxation, Imports and exports	Provides for terms under which the parties may import and export goods while at the Host Nation.
Article VI	Liability	Provides for how to deal with claims other than contractual claims or claims by third parties.
Article VII	Respect of Domestic laws	Provides for how civilian and personnel of the United States Government are to deal with local laws.
Article VIII	Audits and examinations, Access to the Sites	Provides for joint monitoring of the implementation of this Agreement, to observe the progress of activities undertaken pursuant thereto, and to examine the use of goods and services provided under this Agreement
Article IX	Prohibition on Transfers and Unauthorized use	Provides for modalities of transfer and sustainability of goods and services pursuant to the activities under the agreement.
Article X	Contracting	Provides for administration of contracts for purposes of implementing the agreement
Article XI	Settlement of Disputes	Provides for dispute resolution

Article XII	Entry into force and Duration	<p>The Agreement shall enter into force on the date of the last written notification in an exchange of notifications between the Parties by which the Parties notify each other, through diplomatic channels, of the completion of their internal legal procedures required for entry into force.</p> <p>The Agreement shall remain in force, subject to Article XIII (2), for a period of five years from the date of its entry into force.</p> <p>The Agreement may be renewed for an agreed period, upon mutual consultations and consent.</p>
Article 13	Amendment and Termination	Provides for terms for amending or terminating the agreement.

3.1 Object and Subject Matter of The Agreement

The object of the agreement is to enhance cooperation in threat reduction biological engagement between the Republic of Kenya and the United States of America by creating a framework for the exchange of experience and knowledge for the mutual benefit of both Countries. The program will entail mutually agreed projects related to potential biological threats, including naturally occurring diseases, biological attacks, or unintentional releases of biological pathogens or toxins and biological weapons related pathogens and toxins, materials, processes and knowledge.

3.2 Constitutional Implications

The agreement does not propose any amendments to the Constitution.

3.3 Obligations Imposed on Kenya by the Agreement

The agreement requires Kenya to cooperate in the implementation of comprehensive, sustainable and legally embedded national program for biosafety and biosecurity.

3.4 Requirements for the Implementation of the Agreement

The Ministry of Health is expected to work in collaboration with the Ministry of Defence and the Ministry of interior and Coordination of National Government in implementing the agreement.

The Ministry of Health has already constituted a committee incorporating the various Government Agencies to implement the agreement.

3.5 Policy and Legislative Implications

The agreement will be implemented in accordance with the existing domestic legislation. No new policy or legislative interventions are required in its implementation

3.6 Financial Implications

The Cost of the agreement is to be borne by the US Government subject to availability of appropriated funds. The Parties' personnel and other individuals conducting activities under this agreement, who are in the other Party's country purposely for the implementation of this agreement, shall be exempted from income tax of the host Party or any other deductions from their pay allowances and other emoluments and benefits (whether in cash or in kind) paid to them, obtained pursuant to activities under this Agreement.

3.7 Planned Activities

The activities to be undertaken under the agreement will be mutually agreed upon by the two governments based on the scope of cooperation. At present, the following projects are planned at a total cost of US\$ 17 million (Ksh 1.7 billion)

- i. Infrastructural upgrades and constructions at the Isiolo and Kajiado level IV hospital laboratories
- ii. Construction of sample Management facility and other infrastructural upgrades at Central Veterinary Laboratory (CVL), state Department of livestock and Kenya medical Research Institute(KEMRI)
- iii. Infrastructural upgrades at Kenya Veterinary Vaccine production Institute, Embakasi.

Additional projects are envisaged based on the agreements scope of cooperation.

3.8 Process Leading to Adoption of the Agreement

Kenya and the United States have been negotiating the Agreement on biological threat reductions for the past three years. The development of the agreement was necessitated by the need to have a cooperative programme to facilitate efforts to reduce threats from naturally occurring diseases, biological attacks or unintentional release of biological pathogens and toxins and the risks posed by non state actors of bio terrorism.

A survey conducted nationally in about 90 laboratories in 2014 revealed that at least half of the laboratories worked with pathogens that are considered biological threats. It was however noted that majority of the facilities lack requisite measures and capabilities to mitigate the risks associated with the threats. These capabilities include infrastructural aspects, training and technological approaches that together are referred to as biological threat reduction.

The agreement was negotiated by the Ministry of Health. The Ministry adopted a multi-sectoral approach in negotiating the agreement by involving other relevant Government Ministries and Agencies such as the State Law Office, Ministry of Foreign Affairs and International Trade, Ministry of Defence, and the National Treasury.

3.9 Date of Signature:

The agreement was signed on 24th July 2015 during the state visit of the United States President Barrack Obama.

3.10 Whether Expenditure of Public Funds will be incurred in Implementing the Agreement:

The implementation of the agreement envisages no direct financial implications. This is because the United States of America will provide as appropriate and at no cost to the Government of Kenya assistance in support of the implementation of the agreement.

However, Kenya Government will be required to accord tax exemptions to the United States personnel operating in the country and engaged in the implementation of the agreement and the goods and services used in the implementation of the agreement. This will have an implication in terms of loss of tax revenue.

4.0 CONSIDERATION OF THE AGREEMENT ON BIOLOGICAL THREAT REDUCTION BETWEEN KENYA AND THE UNITED STATES

4.1 Submissions by Ministry of Health

While appearing before the National Assembly Departmental Committee on Health, the Ministry of Health responded as follows:-

- (i) The Government of the United States of America and the Government of the Republic of Kenya negotiated and signed the agreement concerning cooperation in threat reduction biological engagement programs on 24th July 2015, during the State visit to Kenya by His Excellency the President of the United States.
- (ii) The agreement was to be executed by the Ministry of Health in collaboration with the Ministry of Defence, and Ministry of Interior and Coordination of National Government for the Government of the Republic of Kenya and the United States Department of Defence for the Government of the United States of America.
- (iii) Biological threat agents are microorganisms or toxins that if accidentally or deliberately released can cause significant disease and death to people and animals, harm to the environment and/or devastate national economies. These agents are typically found in nature, but it is possible that they could be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment. Biological agents can be spread through the air, through water, or in food. Examples include anthrax, pandemic influenza and Ebola virus, among others.
- (iv) Biological knowledge, tools and resources that could constitute biological threats were becoming more widely available around the world, including Kenya. There were growing concerns about potential misuse of biological knowledge and agents for terrorism purposes by biomedical research and associated laboratories.
- (v) International agreements, including the Biological and Toxins Weapons Convention (BWC) and United Nations Security Council Resolution 1540 (UNSCR 1540),

require countries to strengthen their implementation of biosecurity against biological threats.

(vi) The following were the processes that had been undertaken towards the implementation of the Agreement:

- Receipt of the draft agreement by the Government of Kenya
- Inter-ministerial meetings held to provide Kenyan input to the draft agreement
- Negotiations between the Government of Kenya (GOK) and United States Government (USG) held between 16th to 19th June 2015. The delegation of the Government of the Republic of Kenya was led by Dr. Jackson Kioko –the then Head of the Department of Preventive & Promotive Health, while the delegation of the Government of the United States of America was led by Mr. Phil Dolliff – Director of Office of Cooperative Threat Reduction, Bureau of International Security and Non-Proliferation, US Department of State.
- Agreed minutes signed on 19th June 2015.
- Agreement signed on 24th July 2015.
- Formation of the Implementation Committee.
- Presentation of Agreement to Cabinet and Cabinet approval on 1st April 2016.
- Presentation of Cabinet Memorandum to Parliament on 18th August 2016.

(vii) Within Kenya, there are bioscience facilities including advanced human and animal health facilities that routinely work on micro-organisms which are also considered biological threats. These facilities pose both biosafety (accidental) and biosecurity (deliberate) risks.

(viii) In a nationwide laboratory survey conducted, half of the surveyed laboratories worked with pathogens which could be considered biological threats. However, most of these laboratories did not have measures and capabilities including infrastructure, training and technological approaches to mitigate the associated risks.

- (ix) Biological threat reduction is an approach that seeks to protect humans and the environment from exposure to and release of microorganisms or toxins that constituted biological threats. It also includes the containment under which infectious disease agents can be safely manipulated during research or public health activities that must occur in order to combat disease.
- (x) The development of the Agreement was necessitated by the need to have a cooperative program with a multi-sectoral approach to facilitate efforts to reduce the threat from:
- naturally occurring diseases;
 - biological attacks,
 - Unintentional release of biological pathogens and toxins, and
 - The risks posed by non-state actors of bio-terrorism
- (xi) The implementation of the agreement envisaged no direct financial implications to the Government of Kenya because the United States of America will provide as appropriate and at no cost to the Government of the Republic of Kenya assistance in support to the implementation of the Agreement. However, Kenya will be required to accord tax exemptions to the personnel of the Government of the United States of America while in the country purposely to conduct activities under this Agreement; and the goods and services used in the implementation of the Agreement. The activities to be undertaken in the agreement would be mutually agreed on based on the scope of cooperation. The planned projects were at a total cost of US \$17 million (KES 1.7 billion).
- (xii) On the role of other Government Agencies in the implementation of the agreement, the agreement in general seeks to improve health security in the country through initiation and provision of some measures in selected health assets. In participating in the implementation of the agreement, the Ministries of Interior and Defense would therefore be able to better understand, have intelligence and advice on the health security activities being undertaken in the country.
- (xiii) Recent public health events had indicated the need to have more collaboration between the health sector and the security agencies such Ebola outbreak and bioterrorism. Implementation of this Agreement provides a mechanism for enhanced collaboration for these sectors. The Ministry of Interior did issue a statement in April

- i. The Agreement is broad and seeks to provide the general guidelines of engagement between the Kenya and US governments in so far as threat reduction and biological engagement is concerned.
- ii. The Multi-agency Implementation Review Committee will develop specific implementation plans which will provide additional details including taking care of concerns as raised by the Committee and other possible emerging issues.
- iii. A Multi-agency Implementation Review Committee yet to be set up and which will follow the ratification of the Agreement is expected to develop additional subsidiary agreements where necessary to implement specific programs as envisioned in Article two on the Scope of the Cooperation and Article three, sub article three. The latter provides that 'executive agents may conclude agreements and arrangements to implement the agreement.
- iv. The agreement further provides for settlement of disputes where any differences concerning the interpretation or implementation of this agreement shall be resolved solemnly through consultation or negotiation between the parties.

5.2 Specific Observations

5.1.2 Scope of Co-operation

The Committee raised concerns over the ownership of intellectual property rights under the Agreement. The need to define from the onset the mechanisms of engaging on international property rights was highlighted. The mechanism for engagement over Intellectual Property Rights envisaged under Article II (4) of the agreement.

The Committee was however in consensus that the specific implementing agreements envisaged in Article II would further operationalize matters related to intellectual property rights, access and benefits sharing in relation to utilization of biological and generic resources, traditional knowledge and folklore and technology transfer among other activities likely to arise from the activities.

On implementation, the Committee noted that the state Department of Livestock development needed to be part of the implementation committee of the program. This was informed by the fact that some of the programs, for example the construction of sample management facility and other infrastructural upgrades at Central Veterinary

Laboratory (CVL), State Department of livestock and Infrastructural upgrades at Kenya Veterinary Vaccine production Institute in Embakasi fall directly under the purview of the Ministry of Agriculture and Livestock Development.

It was clarified that the Implementing Review Committee to be set up following the ratification of the Agreement would be multi-agency. It would comprise of representation from Ministry of Health, Defense, Interior and Coordination of National Government. Agriculture, livestock and fisheries, State Department of livestock, Foreign affairs, the National Treasury, State Law office, council of Governors and National Commission for Science and Technology an Innovation among others.

5.1.3 Executive Agents and Implementing Agreements

The Committee in its consideration of the Agreement took note of the fact that while the United States has designated the Department of Defence as the Executive Agent for the Government of the United States of America, the executive agent for the Government of Kenya is the Ministry of Health in collaboration with the Ministry of Defense and the Ministry of Interior and Coordination of national Government.

The Committee reservations were that several Government agencies as the executive agent are likely to result in fragmentation in the implementation of the various programs. However the Committee was informed that unlike the US Department of Defense which is known to be multi-disciplinary comprising of health, security, veterinary medicine, biotechnology among other disciplines, the Kenyan executive agencies are distinct hence the incorporation of both the Health, Defense and Interior Ministries.

5.1.4 Taxation, Imports and Exports

As regards taxation, imports and exports, the Committee observed that Article V, of the agreement provides for waiver in income tax, allowances and other emoluments for Parties working in the Country where the activity is being implemented. Further, that the article allows for the importation or exportation of goods and services under the Agreement. The Committees concerns on the risks of exporting the “goods and services” and “pathogens” arising from the Agreement was clarified as follows:

That for the purposes of the agreement the definition of “goods and Services” had been defined independently from “pathogens” in Article 1 of the agreement. “Pathogens according to the Agreement shall refer to pathogens of security concern which include “those agents and toxins included on the Select Agents and Toxins List as well as pathogens that cause emerging and re-emerging diseases capable of becoming threats to security through outbreaks, whether they be naturally occurring or caused by accidental or purposeful release”.

In Article V therefore, there is no mention of “pathogens” to be exported with the section providing for only goods and services. In this case, “goods and services” shall refer to all materials, including biological materials and related information, equipment, supplies, commodities, facilities, services, funds, documents, records, technology, training, construction, property, personal property etc.

5.1.5 Audits and Examinations, Access to the Sites

The Committee observed and raised reservations on the Article on audits and examinations and access to sites. The Committee indicated that access to sites by the other Party was likely to compromise and expose the Country to further potential threats while compromising the Nation’s sovereignty. It was however noted that Article VIII on audits and examinations, access to the sites has provided for adequate arrangement on how the audits and examinations are to be undertaken. For example:

- (a) Provision for written notification which would include scope of the audit and the inspection prior to the visit.
- (b) Written confirmation for inspection or audit and the inspected Party may give input to the scope of the audit
- (c) A copy of any official audit or inspection report prepared jointly
- (d) A party that is subject to the inspection or provide response

5.1.6 Liability

The Committee raised concerns on the Article on liability where except for contractual claims; parties were not expected to bring legal proceedings against each other’s personnel, contractors and contractors, personnel for damage to each other’s property.

This was however noted that the Article also provides for third party liabilities including possible compensation.

6.0 COMMITTEE RECOMMENDATIONS

The Committee recommends that:

1. The National Assembly approves the ratification of the agreement as it is in the interest of the Country in line with the World Health Organization - International Health Regulations in addressing biological threats and pathogens.
2. The Multi-agency Implementing Committee (envisioned in Article VII- sub-article 3) be established immediately after the ratification of the Agreement to facilitate the effective implementation of the agreement as envisage in Article II.
3. The Agencies involved in the implementation should develop the requisite capacity to be able to effectively implement this agreement.
4. All laws on waiver of taxes be taken into consideration when implementing the agreement.
5. The Implementing Review Committee be constituted and should develop a mechanism for reporting back to Parliament on the status of implementation of the agreement.
6. The Ministry of Health together with the other state agencies charged with handling of pathogens should develop the standard national list of pathogens.
7. The Ministry of Health should provide a list of specific goods and services under this agreement to be exempt from taxes, duties, levies.
8. The State Law Office should fast track the draft Biosecurity Bill to be passed by Parliament so as to provide a legal framework on which to anchor issues of bio safety and bio security.

Signed.....

Date.....

17/11/2016

THE HON. DR. RACHAEL NYAMAI, M.P.
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

DC-H: DEPARTMENTAL COMMITTEE ON HEALTH

ATTENDANCE REGISTER

AGENDA:


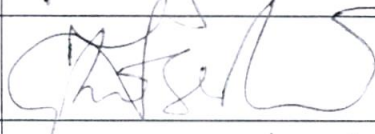
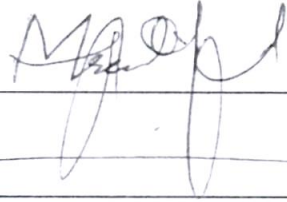

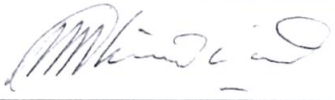
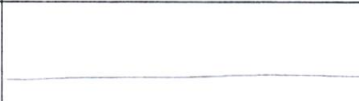
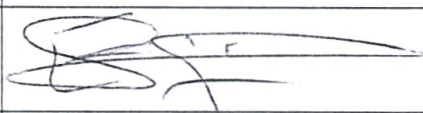
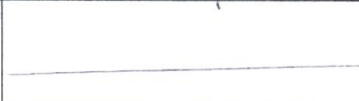
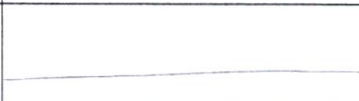
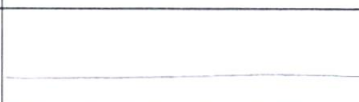
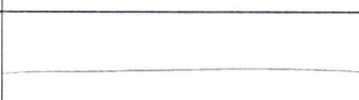
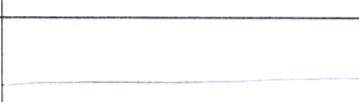

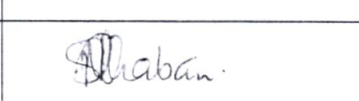
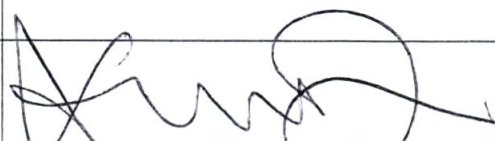
MEETING WITH THE PS DEFENCE ON THE AGREEMENT BETWEEN KENYA AND USA

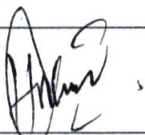

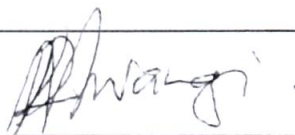
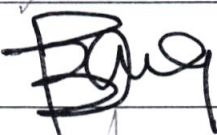





ADOPTION OF REPORT

DATE: 8th Nov 2016

VENUE:

4th floor

	HON. MEMBER	SIGNATURE
1.	The Hon. Dr. Rachel Nyamai, M.P. Chairperson	
2.	The Hon. Dr. Robert Pukose, M.P. Vice Chairperson	
3.	The Hon. Alfred Agoi, M.P.	
4.	The Hon. Alfred Sambu, M.P.	
5.	The Hon. David Karithi, M.P.	
6.	The Hon. Dr. Dahir D. Mohamed, M.P.	
7.	The Hon. Dr. Eseli Simiyu, CBS, M.P.	
8.	The Hon. Jared Opiyo, M.P.	
9.	The Hon. Dr. Enoch Kibunguchy, M.P.	
10.	The Hon. Dr. James Murgor, M.P.	
11.	The Hon. Dr. James Nyikal, M.P.	
12.	The Hon. Dr. James O. Gesami, M.P.	
13.	The Hon. Dr. Naomi Shaban, M.P.	
14.	The Hon. Dr. Patrick Musimba, MP	
15.	The Hon. Dr. Stephen Wachira, M.P.	

	HON. MEMBER	SIGNATURE
16.	The Hon. Dr. Susan Musyoka, M.P.	
17.	The Hon. Fred Outa, M.P.	
18.	The Hon. Hassan Aden Osman, M.P.	
19.	The Hon. James Gakuya, M.P.	
20.	The Hon. John Nyaga Muchiri, HSC, M.P.,	
21.	The Hon. Kamande Mwangi, M.P.	
22.	The Hon. Leonard Sang, M.P.	
23.	The Hon. Michael Onyura, M.P.	
24.	The Hon. Robert Mbui, M.P.	
25.	The Hon. Mwinga Gunga, M.P.	
26.	The Hon. Paul Koinange, M.P	
27.	The Hon. Raphael Milkau Otaalo, M.P.	
28.	The Hon. Stephen M. Mule, MP	
29.	The Hon. Zipporah Jesang, M.P.	

MINUTES OF THE 85TH SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD ON THURSDAY 27TH OCTOBER, 2016, IN THE 2TH FLOOR BOARD ROOM, PROTECTION HOUSE, PARLIAMENT BUILDINGS AT 10.00 AM.

PRESENT

1. **The Hon. Dr. Racheal Nyamai, M.P. (Chairperson)**
2. The Hon. Jared Opiyo, M.P.
3. The Hon. Dr. James Nyikal, M.P.
4. The Hon. Dr. Eseli Simiyu, CBS, M.P.
5. The Hon. Alfred Agoi, M.P.
6. The Hon. Fred Outa, M.P.
7. The Hon. Dr. Naomi Shaban, M.P.
8. The Hon. Dr. James O. Gesami, M.P.
9. The Hon. Dr. Dahir D. Mohamed, M.P.
10. The Hon. David Karithi, M.P.
11. The Hon. Michael Onyura, M.P.
12. The Hon. Mwinga Gunga, M.P.
13. The Hon. Kamande Mwangi, M.P.
14. The Hon. James Gakuya, M.P.
15. The Hon. Robert Mbui, M.P.
16. The Hon. John Nyaga Muchiri, M.P.
17. The Hon. Leonard Sang, M.P.
18. The Hon. Zipporah Jesang, M.P.

ABSENT WITH APOLOGY

1. The Hon. Dr. Robert Pukose, M.P. (Vice Chairperson)
2. The Hon. Dr. Enoch Kibunguchy, M.P.
3. The Hon. Dr. James Murgor, M.P.
4. The Hon. Dr. Stephen Wachira, M.P.
5. The Hon. Paul Koinange, M.P.
6. The Hon. Hassan Aden Osman, M.P.
7. The Hon. Raphael Milkau Otaalo, M.P.
8. The Hon. Stephen M. Mule, M.P.
9. The Hon. Dr. Patrick Musimba, M.P.
10. The Hon. Dr. Susan Musyoka, M.P.
11. The Hon. Alfred Sambu, M.P.

IN ATTENDANCE

National Assembly Secretariat

1. Mr. Dennis Mogare - Third Clerk Assistant.
2. Ms. Ruth Mwhaki - Third Clerk Assistant.

MIN.NO. DCH 348/2016: PRELIMINARIES.

The Chairperson called the meeting to order at 10.30am and said a prayer. She then stated that the purpose of the meeting was to consider and adopt the report on the ratification of the agreement between the governments of the Republic of Kenya and the Government of the United States of America concerning cooperation in threat reduction biological engagement programs.

MIN.NO. DCH 349/2016: CONFIRMATION OF MINUTES

Minutes of the 72nd Sitting held on Tuesday 13th September, 2016 at 10.00 a.m. were confirmed as the true record of the Committee's deliberations after being proposed and seconded by Hon. Fred Outa, M.P. and Hon. Jared Opiyo, M.P. respectively.

Minutes of the 73rd Sitting held on Wednesday 14th September, 2016 at 9.00 a.m. were confirmed as the true record of the Committee's deliberations after being proposed and seconded by Hon. Jared Opiyo, M.P. and Hon. Fred Outa, M.P. respectively.

Minutes of the 74th Sitting held on Thursday 15th September, 2016 at 10.00 a.m. were confirmed as the true record of the Committee's deliberations after being proposed and seconded by Hon. Jared Opiyo, M.P. and Hon. Fred Outa, M.P. respectively.

Minutes of the 75th Sitting held on Thursday 15th September, 2016 at 2.30 p.m. were confirmed as the true record of the Committee's deliberations after being proposed and seconded by Hon. Jared Opiyo, M.P. and Hon. Fred Outa, M.P. respectively.

Minutes of the 76th Sitting held on Tuesday 4th October, 2016 at 10.00 a.m. were confirmed as the true record of the Committee's deliberations after being proposed and seconded by Hon. Dr. James Nyikal, M.P. and Hon. Jared Opiyo, M.P. respectively

MIN.NO. DCH 350/2016: MATTERS ARISING

The following matters arose from the previous Minutes:

1. Under **MIN.NO. DCH 301/2016:**

The Committee noted that the record in the Minute indicating non representation of the Ministry during the Meeting with GAVI was erroneous and that the correct position was that the Ministry had been represented by a junior officer during the said meeting.

2. Under **MIN.NO. DCH 303/2016:**

The Committee noted that the invitation to the Health summit held in State House was to the Chairperson in her personal capacity and not to the Committee. The Chairperson informed the meeting that she had attended the summit but did not make any statement.

The Committee resolved that in future, such invitations should be made to the Committee through the Clerk's office to ensure the Committee's participation.

3. Under **MIN.NO. DCH 306/2016:**

The Committee noted that the record in the Minute indicating that content of select agents and toxin list was considered to be very confidential for security purposes was incorrect, and that during the meeting with the Ministry regarding the agreement; the Committee had been informed that the country did not have a select agents and toxin list.

MIN.NO. DCH 351/2016: CONSIDERATION AND ADOPTION OF THE REPORT ON THE RATIFICATION OF THE AGREEMENT BETWEEN THE GOVERNMENTS OF THE REPUBLIC OF KENYA AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA CONCERNING COOPERATION IN THREAT REDUCTION BIOLOGICAL ENGAGEMENT PROGRAMS.

The Committee considered the report and noted that there were several concerns that had not been adequately addressed in as far as ensuring the security of the country against terror threats. It noted that ratifying the agreement could expose the country to biological warfare. The Committee however noted that it was important to build capacity in the country to deal with pathogens and biological weapons.

After lengthy deliberations, the Committee resolved that the Principal Secretary for Defence be invited to clarify on the following:

1. The possible consequences of not ratifying the agreement in regard to the security of the country ,and:
2. The security implications of ratifying the agreement in light of terror threats facing the country

MIN.NO. DCH 352/2016: ANY OTHER BUSINESS

1. The Committee took note of concerns raised through the media regarding the alleged loss of Ksh.5 billion by the Ministry of Health through a leaked internal Audit report for the Ministry.

The Committee noted that it was necessary that it interrogates the budget implementation for the Ministry in light of the funds allegedly misappropriated.

The Committee resolved that the budget office should brief the Committee on budget implementation for the Ministry on Tuesday 1st November and thereafter meet with the Cabinet Secretary for Health on Thursday 4th November regarding the allegations of misappropriation of Funds in the Ministry.

The Report on the Agreement between the Government of Kenya and the Government of the United States of America Concerning Cooperation in Threat Reduction Biological Engagement Programs was considered and members deferred its adoption after recommending the following amendments:

1. Add the requirement for quarterly reporting to parliament in part "c" of the recommendations.
2. Add a new recommendation that shall read as follows:
"The agencies to be involved in implementation of the agreement should develop adequate capacity to ensure effective implementation of the agreement."
3. Add a new recommendation that shall read as follows:
"The implementing agencies should ensure that toxins, pathogens and biological agents are not exported from the facilities envisaged under the agreement (Article XI (1)) unless with mutual consent."

MIN.NO. DCH 326/2016: ANY OTHER BUSINESS

The Committee resolved to visit, within a month from the date of the meeting, the Garissa and Meru County Hospitals to assess:

- a) The efficacy of conditional grants allocated to the facilities.
- b) The progress of the Manged Equipment Service Project at the facilities.

MIN.NO. DCH 327/2016: ADJOURNMENT

There being no other business, the meeting was adjourned at 12.55 pm.

SIGNED:


HON (DR.) RACHAEL NYAMAI, M.P.
CHAIRPERSON

DATE: 17 / 11 / 2016

MINUTES OF THE 73RD SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD ON WEDNESDAY 14TH SEPTEMBER, 2016, IN THE AMANI CONFERENCE ROOM, SERENA HOTEL AT 9.00 AM.

PRESENT

1. **The Hon. Dr. Racheal Nyamai, M.P. (Chairperson)**
2. **The Hon. Dr. Robert Pukose, M.P. (Vice Chairperson)**
3. The Hon. Dr. James Nyikal, M.P.
4. The Hon. Hassan Aden Osman, M.P.
5. The Hon. Leonard Sang, M.P.
6. The Hon. Paul Koinange, M.P.
7. The Hon. Fred Outa, M.P.
8. The Hon. Mwinga Gunga, M.P.
9. The Hon. Jared Opiyo, M.P.
10. The Hon. Michael Onyura, M.P.
11. The Hon. Dr. Stephen Wachira, M.P.

ABSENT WITH APOLOGY

1. The Hon. Dr. Enoch Kibunguchy, M.P.
2. The Hon. Dr. Eseli Simiyu, CBS, M.P.
3. The Hon. Dr. Dahir D. Mohamed, M.P.
4. The Hon. Dr. James O. Gesami, M.P.
5. The Hon. Kamande Mwangi, M.P.
6. The Hon. Stephen M. Mule, M.P.
7. The Hon. Robert Mbui, M.P.
8. The Hon. Zipporah Jesang, M.P.
9. The Hon. Dr. Patrick Musimba, M.P.
10. The Hon. Dr. Naomi Shaban, M.P.
11. The Hon. Dr. Susan Musyoka, M.P.
12. The Hon. Alfred Sambu, M.P.
13. The Hon. Alfred Agoi, M.P.
14. The Hon. David Karithi, M.P.
15. The Hon. James Gakuya, M.P.
16. The Hon. Raphael Milkau Otaalo, M.P.

IN ATTENDANCE

National Assembly Secretariat

1. Ms. Esther Nginyo - Third Clerk Assistant.
2. Ms. Sande Marale - Senior Research Officer.

Ministry of Health

1. Dr. Nicholas Muraguri - Principal Secretary
2. Dr. Kioko - Director of Medical Services

3. Dr. Ayagah Isabella
4. Ibrahim A. Maalim
5. Dr. Athman Mwatondo
6. William Okoyo
7. Winjoy Mureithi

Kemri

1. Dr. Gerald Mkoji - Director
2. Nicholas Mwikwabe
3. Milkah Mwangi

Ministry of Agriculture, Livestock and Fisheries

1. Dr. Christopher Wanga
2. Dr. Jane Wachira

State Law Office

1. Mercy Olando

Department of Threat Reduction Agency - Kenya

1. Emily Onyancha

MIN.NO. DCH 305/2016: PRELIMINARIES.

The Chairperson called the meeting to order at 9.30 am and a word of prayer was said followed by self-introduction of all those who were present. The Principal Secretary, Ministry of Health, The Director of Medical Services and the Chairperson gave their opening remarks.

MIN.NO. DCH 306/2016: CONSIDERATION OF THE AGREEMENT BETWEEN THE GOVERNMENT OF KENYA AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA CONCERNING COOPERATION IN THREAT REDUCTION BIOLOGICAL ENGAGEMENT PROGRAMS.

The Ministry of Health represented by the National Public Health Laboratories and the Kenya Medical Research Institute, and the Ministry of Agriculture, Livestock and Fisheries represented by the State Department of Livestock briefed the Committee on the justification of the agreement and the proposed activities envisaged under the Agreement as follows;

1. Presentation by KEMRI

Dr. Gerald Mkoji, Director, KEMRI briefed the Committee as follows that;

- I. KEMRI's Involvement in the Promotion of Global Health Research Initiatives included

- Regional laboratory capacity building in operation research under the East African Public Health Laboratory networking project (EAPHLN).
 - Research on Neglected Tropical Diseases (NTDs)
 - WHO designated Centre of excellence in Malaria, Nutrition and Virology
 - WHO Collaborating Centre for HIV/AIDS, Tropical Diseases Research, Polio Immunization, Viral Hemorrhagic Fevers and Anti-Microbial Resistance (WHO-NET).
 - Africa Network for Drugs and Diagnostics Innovation (ANDI) Centre of Excellence in the Manufacturing and Development of Diagnostic Kits
- ii. Kemri's Capacity to Support Disease Surveillance and Response to Outbreaks in the region was commendable in terms of expertise in epidemiological studies, disease surveillance, and outbreaks, and Lab capacity to support disease surveillance and response to outbreaks including Dengue, Chikungunya Virus, H1N1 Flu, Yellow Fever, Rift Valley Fever, Ebola, Aflatoxicosis.
- iii. Kemri collaboration with the Department of Threat Reduction Agency (DTRA) began on 12th November, 2010, **USA Sen. Richard Lugar**; when the Senate Leader for Foreign Relations Committee, led a congressional delegation on a visit to Kenya. The tour focused on the increasing alert on threat from bioterrorism.
- iv. Defense threats analysts were concerned that the security situation in the East Africa region too weak to withstand threats from terrorist groups.
- v. Due to its research and disease surveillance mandate, KEMRI handles a variety of biological infectious agents that can potentially be used for bioterrorism or cause serious illnesses. However, there had been concerns that the security and safety of biological samples held at KEMRI is inadequate.
- vi. Even though there had been no terrorist threats against KEMRI, it was important to secure the facilities and the samples. This was necessary to ensure that pathogens that could potentially be used for terrorist activities are securely stored, so that they could not accidentally escape or end up in the wrong hands.
- vii. It was due to such concerns that DTRA experts came to assess the KEMRI facilities to determine the levels of vulnerability. Several observations were made following a survey conducted at KEMRI by DTRA and other collaborating US agencies. They included:
- a) Crowded Corridors
 - b) Crowded laboratories

- c) Lack of adequate Waste Management and Storage
 - d) Sample inventory & management
 - e) Location of KEMRI Close to an Informal Settlement
 - f) Need for capacity building
- viii. Based on the survey DTRA made recommendations that KEMRI Strategic & Master Plans inform where to locate function on campus. The following KEMRI-DTRA Proposed Project to mitigate the findings:
- Sample Management & Reception Facility (SMRF)
 - Upgrading of Incinerators
 - Renovation and modification of existing labs to reorganize the laboratories
 - New office areas separated from lab space
 - New Multi-Purpose Buildings
 - New facility layout to create better flow within the lab space and a new open lab design
 - Capacity building in preparation for the completion of the project

2. Presentation by the National Public Health Labs:

Mr. Mamo Umuro, Head of the National Public Health Labs made the following presentation to the Committee that:

- i. The Negotiations on agreement begun in 2012; the drafted agreement was shared through diplomatic channels;
- ii. The Ministry of Foreign Affairs called for and several inter-ministerial meetings in which inputs were given to the Agreement;
- iii. On 16 - 19 June 2015 the Kenya and USA delegation met in Naivasha and carried out the final negotiations of the Agreement;
- iv. The Agreement was signed on 24th July 2015 during the visit by H.E President Barrack Obama;
- v. The Agreement was presented to cabinet in during the 4th cabinet meeting on 1st April 2016. The Cabinet directed CS health to present the agreement in parliament for ratification which was done on 18th August 2016;
- vi. The issues of concern were the public health scenarios such as the preparedness to respond to viral haemorrhagic fevers such ebola, dangerous pathogens such as anthrax that are cultured in the labs and that could easily be accessed or fall into the wrong hands, security of the water supplies that could be easily contaminated by easily accessible pathogens and distribution of contaminated food with dangerous pathogens;
- vii. The NPHL'S (MOH) Biosafety & Biosecurity Program Goals as contemplated by the Agreement were meant to:
 - Strengthen laboratory Biosafety and Biosecurity systems at national and county levels;
 - Undertake appropriate training and competence development programs to support Bio-risk management;

- Develop processes and tools for implementing a bio risk management systems;
 - Coordination of MOH Biosafety/Biosecurity national and partner supported activities;
 - Offer Technical support to counties and implementing partners;
 - Monitor and ensure adherence of Biosafety/Biosecurity standards and Practices; and
 - Regularly update relevant Biosafety/Biosecurity policy guidelines.
- viii. The NPHL had some Key achievements towards biosafety, which included:
- Development of Biosafety/Biosecurity training curriculum;
 - Coordination of Training laboratory Health Care Workers on laboratory Biosafety and Biosecurity at national and across counties;
 - 6 Biomedical technologists internationally trained on certification of Biosafety Cabinets locally.
 - Supported ISO 15189 accreditation of medical laboratories - 10 laboratories have successfully completed this process. Other labs in the country have enrolled for accreditation process
 - Improved Biosafety/Bio-security practices in the medical laboratories
- ix. NPHL was however faced with various Challenges which included:
- Weak Pathogen repository and inventory systems.
 - Weak Chemical management, inventory safety and disposal systems/guidelines
 - Training of other Cadres of Health Care Workers.
 - Inadequate funding to strengthen implementation of Biosafety/Biosecurity systems in medical laboratories
 - Lack of Biorisk management training in regions not currently covered by PEPFAR- funded partners
 - Lack of Biosafety/Biosecurity annual refresher training
- x. With the ratification of the Agreement, the following would be the Foreseen Benefits;
- Safeguarded inventory of identified dangerous pathogens in restricted facilities and license, monitor, track highly toxic biological materials;
 - Whole-of-government specific Biosecurity legislation and strategic plan;
 - A comprehensive, sustainable and legally embedded national oversight program for Biosafety and Biosecurity informed by the bioscience bill;
 - Whole-of-government integrated Biorisk curriculum and subsequent Bio-risk trainings for regions currently not covered by PEPFAR funded partners;
 - Capacity building on standard BSL3 safety practices and Bio-risk management trainings for the new laboratories at NPHL and counties through exchange and mentorships programs;
 - Strengthened laboratory biosafety and biosecurity systems including physical infrastructure of labs at national and county levels through sustained funding.
- xi. The Proposed activities in the Agreement would include: Isiolo County Referral Hospital and Kajiado County Referral Hospital

The Committee raised the following concerns regarding the Agreement;

- i. The issue of why United States has designated the Department of Defence as the executive Agent for the Government of the United States of America, while the Government of Kenya is the Ministry of Health in collaboration with the Ministry of Defense and the Ministry of Interior and Coordination of national Government.
- ii. The need to have the goods to be exported and imported under Article V restricted to those used in the implementation of the agreement and personal belongings of personnel involved.
- iii. The Article VI on liability was unclear.
- iv. There was need for clarification on mechanism of audits and examination and the access to site.
- v. The content of the Select Agents and Toxins List held by the Kenyan Government that is the target for the assistance envisaged under Article I (3) (d) of the agreement.
- vi. The level of capacity building for the personnel envisaged in the Agreement.

The Ministry Clarified on the issues raised by the Committee that:

- i. The cooperation with the US Department of Defence was necessitated by the fact that biological threat is a security issue however; the projects anticipated under the Agreement fell under the purview of the Ministry of Health. There is therefore need to ring-fence the areas of support to protect the interests of Kenyans under the subsidiary agreements.
- ii. On the goods to be exported and imported as anticipated under Article V, Article 1 paragraph 3 defines the terms 'goods and services' and 'pathogens' therefore protecting the exportation of any biological materials.
- iii. On liability in Article VI, the finer details on its implementation would be included in the document on the Terms of Reference.
- iv. On the content of select agents and toxin list, the list was considered to be very confidential for security purposes.
- v. On the level of capacity building for the personnel as envisaged in the Agreement, the details of the nature of the capacity building would be defined in the Memorandum of Understanding for its implementation.

MIN.NO. DCH 307/2016:

COMMITTEE'S OBSERVATIONS

The Committee observed the following, that;

1. There were weak inventory and repository systems for biological materials in the country and therefore there was need for capacity building to strengthen these systems for security and safety measures.
2. There was need to ensure that the biological materials movement is monitored through formal mechanisms and using real time inventory management system for security purposes.
3. Although Kenya was considered a hub for disease control in the region due to its capacity in its research institutions, there was need to strengthen its capacity to secure the gains so far made in securing and detection of pathogens and to keep up with the

emerging issues in biological threat as well as meet the World Health Organization Commitment on pathogen security.

4. The Agreement was drawn arising from the previous Memoranda of Understanding which had previously been signed between the US Government and various government Agencies that were considered weak. The Agreement was meant to strengthen the weaknesses.
5. There was need for the regulatory bodies for personnel in biological sciences to ensure that proper data is kept and personnel are registered annually for ease their tracking.
6. The signing of the Agreement with the US Government would expose Kenya's information and therefore is need to ensure that the interest of the country are well protected in the subsidiary agreements.
7. Upon ratification of the Agreement, the Implementation Review Committee should be formed as a matter of urgency before the implementation of the Agreement.
8. There should be proper mechanisms of reporting back to Parliament on the implementation on the Agreement by the Implementation Review Committee through the Ministry of Health. This mechanism should be clearly stipulated in the Terms of Reference Document.

MIN.NO. DCH 308/2016: ADJOURNMENT

There being no other business, the meeting was adjourned at 2.05 pm.

SIGNED:

HON (DR.) RACHAEL NYAMAI, M.P.
CHAIRPERSON

DATE: 27th October, 2016

MINUTES OF THE 62ND SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD ON THURSDAY, 18TH AUGUST, 2016, IN THE MINI CHAMBER, COUNTY HALL, PARLIAMENT BUILDINGS, AT 10.00 AM.

PRESENT

1. **The Hon. Dr. Racheal Nyamai, M.P. (Chairperson)**
2. **The Hon. Dr. Robert Pukose, M.P. (Vice Chairperson)**
3. The Hon. Dr. James Murgor, M.P.
4. The Hon. Alfred Agoi, M.P.
5. The Hon. John Nyaga Muchiri, M.P.
6. The Hon. Dr. James Nyikal, M.P.
7. The Hon. Paul Koinange, M.P.
8. The Hon. Dr. Stephen Wachira, M.P.
9. The Hon. Kamande Mwangi, M.P.
10. The Hon. David Karithi, M.P.
11. The Hon. Raphael Milkau Otaalo, M.P.
12. The Hon. Leonard Sang, M.P.
13. The Hon. Dr. Enoch Kibunguchy, M.P.
14. The Hon. Dr. Dahir D. Mohamed, M.P.
15. The Hon. Michael Onyura, M.P.
16. The Hon. Fred Outa, M.P.
17. The Hon. Hassan Aden Osman, M.P.
18. The Hon. Mwinga Gunga, M.P.
19. The Hon. Dr. James O. Gesami, M.P.
20. The Hon. Stephen M. Mule, M.P.
21. The Hon. James Gakuya, M.P.

ABSENT WITH APOLOGY

1. The Hon. Dr. Naomi Shaban, M.P.
2. The Hon. Jared Opiyo, M.P.
3. The Hon. Zipporah Jesang, M.P.
4. The Hon. Robert Mbui, M.P.
5. The Hon. Dr. Eseli Simiyu, CBS, M.P.
6. The Hon. Dr. Susan Musyoka, M.P.
7. The Hon. Dr. Patrick Musimba, M.P.
8. The Hon. Alfred Sambu, M.P.

IN ATTENDANCE

National Assembly Secretariat

1. Ms. Esther Nginyo - Third Clerk Assistant.
2. Ms. Ruth Mwhaki - Third Clerk Assistant
3. Mr. Dennis Mogare - Third Clerk Assistant.
4. Marlene Ayiro - Legal Counsel
5. Albert Ndemo - Serjeant-At-Arms

Ministry of Health

1. Dr. Cleopa Maillu - Cabinet Secretary
2. Dr. Peace Masinde
3. Dr. Gerald Mkonji
4. Dr. Amoth
5. I.M. Abdi
6. Milkah Mwangi
7. Mamo Umuro

Ministry of Defence

1. Amb. Kirimi Kaberia - Principal Secretary
2. Peter K. Mbugua
3. G.F Sakwa

National Treasury

1. Wanyambura Mwambia - Ag. Director, Macro and Fiscal Affairs

Office of the Attorney General

1. Lulu Hayanga - State Counsel

Ministry of Foreign Affairs

1. Dennis Muhambe - Foreign Service Officer

MIN.NO. DCH 259/2016: PRELIMINARIES.

The Chairperson called the meeting to order at 10.20 am and a prayer was said by Hon. Dr. James Nyikal, M.P. She then stated that the agenda of the meeting was meeting with the following regarding the agreement between the Government of Kenya and the Government of the United States of America Concerning Cooperation in Threat Reduction Biological Engagement Programs: the Attorney General, Cabinet Secretary, Ministry of Health, Cabinet Secretary, National Treasury, Cabinet Secretary, Ministry of Foreign Affairs and International Trade, Cabinet Secretary, Ministry of Defence and Principal Secretary, State Department of Interior and Border Management.

MIN.NO. DCH 260/2016: MEETING WITH VARIOUS STAKEHOLDERS, REGARDING THE AGREEMENT BETWEEN THE GOVERNMENT OF KENYA AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA CONCERNING COOPERATION IN THREAT REDUCTION BIOLOGICAL ENGAGEMENT PROGRAMS.

The Chairperson while inviting the stakeholders to make their remarks noted that State Department of Interior and Border Management had sent an apology letter indicating that they were engaged elsewhere in official engagement. Further, she noted that the Ministry of Foreign Affairs and International Trade and the Office of the Attorney General were

represented by officers who did not have authority letters indicating that they were representing their institutions heads. The Ministry of Health, the Ministry of Defence and the National Treasury were represented.

She then invited presentations in the following order: Cabinet Secretary, Ministry of Health, Principal Secretary, Ministry of Defence and the Cabinet Secretary Representative, National Treasury.

Presentation by the Cabinet Secretary, Ministry of Health

The Cabinet Secretary, Ministry of Health, Dr. Cleopa Maillu appeared before the Committee and informed it as follows:

1. The Government of the United States of America and the Government of the Republic of Kenya negotiated and signed an Agreement Concerning Cooperation in Threat Reduction Biological Engagement Programs on 24th July 2015, during the State Visit to Kenya by His Excellency the President of the United States of America.
2. The Agreement was to be executed by The Ministry of Health in collaboration with the Ministry of Defence, and Ministry of Interior and Coordination of National Government for the Government of the Republic of Kenya and the United States Department of Defence for the Government of the United States of America.
3. Biological threat agents are microorganisms or toxins that if accidentally or deliberately released can cause significant disease and death to people and animals, harm to the environment and/or devastate national economies. These agents are typically found in nature, but it is possible that they could be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment. Biological agents can be spread through the air, through water, or in food. Examples include anthrax, pandemic influenza and Ebola virus, among others.
4. Biological knowledge, tools and resources that can constitute biological threats were becoming more widely available around the world, including Kenya. There were growing concerns about potential misuse of biological knowledge and agents for terrorism purposes by biomedical research and associated laboratories.
5. International agreements, including the Biological and Toxins Weapons Convention (BWC) and United Nations Security Council Resolution 1540 (UNSCR 1540), require countries to strengthen their implementation of biosecurity against biological threats.
6. The following are the processes that have been undertaken towards the implementation of the Agreement:
 - Receipt of the Draft Agreement by the Government of Kenya
 - Inter-ministerial meetings held to provide Kenyan input to draft Agreement
 - Negotiations between the GOK and USG (16th to 19th June 2015). The delegation of the Government of the Republic of Kenya was led by Dr. Jackson Kioko –the then head of the Department of preventive & promotive health, while the delegation of the Government of the United States of America was led by Mr. Phil Dolliff – Director of

Office of Cooperative Threat Reduction, Bureau of International Security and Non-Proliferation, US Department of State.

- Agreed minutes signed on 19th June 2015.
 - Agreement signed on 24th July 2015.
 - Formation of the Implementation Committee.
 - Presentation of Agreement to Cabinet and Cabinet approval on 1st April 2016.
 - Presentation of Cabinet Memorandum to Parliament on 18th August 2016.
7. Within Kenya, there are bioscience facilities including advanced human and animal health facilities that routinely work on microorganisms which are also considered biological threats. These facilities pose both biosafety (accidental) and biosecurity (deliberate) risks.
 8. In a nationwide laboratory survey conducted, half of the surveyed laboratories worked with pathogens which could be considered biological threats. However, most of these laboratories did not have measures and capabilities including infrastructure, training and technological approaches to mitigate the associated risks.
 9. Biological threat reduction is an approach that seeks to protect humans and the environment from exposure to and release of microorganisms or toxins that constitute biological threats. It also includes the containment under which infectious disease agents can be safely manipulated during research or public health activities that must occur in order to combat disease.
 10. The development of the Agreement was necessitated by the need to have a cooperative program with a multi-sectoral approach to facilitate efforts to reduce the threat from:
 - naturally occurring diseases;
 - biological attacks,
 - Unintentional release of biological pathogens and toxins, and
 - The risks posed by non-state actors of bio-terrorism
 11. The objectives of the Agreement include: To enhance the Government of Kenya's capability to identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens; and to enhance the Government of Kenya's capability to rapidly and accurately survey, detect, diagnose, and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements.
 12. The activities to be undertaken under the Agreement will be mutually agreed upon by the two governments based on the scope of cooperation. The following projects are planned at a total cost of US \$17 million (KES 1.7 billion);
 - Infrastructural upgrades and constructions at the Isiolo and Kajiado Level IV Hospital Laboratories.
 - Construction of Sample Management Facility and Other Infrastructural upgrades at Central Veterinary Laboratory (CVL), State Department of Livestock and the Kenya Medical Research Institute (KEMRI).

- Infrastructural upgrades at the Kenya Veterinary Vaccine Production Institute, Embakasi.

More projects are envisaged based on the Agreement's scope of cooperation.

13. The implementation of the Agreement envisages no direct financial implications to the Government of Kenya because the United States of America will provide as appropriate and at no cost to the Government of the Republic of Kenya assistance in support to the implementation of the Agreement. However, Kenya will be required to accord tax exemptions to the personnel of the Government of the United States of America while in the country purposely to conduct activities under this Agreement; and the goods and services used in the implementation of the Agreement. This will have a financial implication in terms of loss of tax revenue. The activities to be undertaken in the agreement will be mutually agreed on based on the scope of cooperation. The projects are planned at a total cost of US \$17 million (KES 1.7 billion).
14. On the role of other government agencies in the implementation of the agreement, the Agreement in general seeks to improve health security in the country through initiation and provision of some measures in selected health assets. In participating in the implementation of the Agreement, the Ministries of Interior and Defense will therefore be able to better understand, have intelligence and advice on the health security activities being undertaken in the country.
15. Recent public health events have indicated the need to more collaboration between the health sector and the security agencies such Ebola outbreak and bioterrorism. Implementation of this Agreement provides a mechanism for enhanced collaboration for these sectors. The Ministry of Interior did issue a statement in April 2016, pledging to provide security to some sensitive health assets such as KEMRI laboratories.
16. In the Implementation of the Agreement, the counterpart to Ministry of Health (MoH) from the US side is the Department of Defense (DOD). While the US DOD has a developed health sector, the Kenya DoD still works closely with MoH on health aspects. The defence team will therefore complement MoH on the Kenya side by incorporating both health and security aspects.

Presentation by the Principal Secretary, Ministry of Defense

The Principal Secretary Ministry of Defense, Amb. Kirimi Kaberia appeared before the Committee and informed it as follows:

1. The Agreement was negotiated between the governments of Kenya and the USA from 16th - 19th June, 2015. In the negotiations, the Ministry of Defense was represented by a legal officer and a medical officer.
2. The Agreement creates a framework under which the US government could support Kenya's programs on biosafety and biosecurity which could be mutually agreed on. The programs would extend to supporting human resource capacity development in biosafety and biosecurity.
3. The position of the Ministry of Defense was that the agreement is potentially beneficial to Kenya and the Ministry of Defense and therefore should be supported and ratified.

Presentation by the Ag. Director, Macro and Fiscal Affairs, National Treasury

The Ag. Director, Macro and Fiscal Affairs, National Treasury, Mr. Mwanyambura Mwambia, appeared before the Committee and informed it that:

1. On matters relating to tax as contained in the Agreement, the consideration for exemption is based on
 - i. The understanding between the donor and the recipient of the supported that is being provided that the support provided will not be taxed; and
 - ii. The availability of the tax provisions in the legislation.
2. The exemption provisions in the Agreement are covered in the tax laws and therefore can be granted as guided by Section 210 of the Constitution of Kenya, 2010.
3. In granting the exemption, the Cabinet Secretary, National Treasury, will require the Ministry of Health to provide a list of the goods and services that will be strictly for the implementation of the project. It is the Ministry of Health that will have the responsibility of determining the goods and services required for the implementation of the project.
4. Once the master list has been granted approval for exemption, the specific letter to the Kenya Revenue Authority will be processed on a case by case basis. This will ensure that only those items that are in the master list are granted exemption.
5. The exemption will be valid for the period of implementation of the project; and
6. The goods that will have been imported into Kenya on temporary basis will qualify for re-exportation. The details of such goods will need to be agreed between the Ministry of Health and the donor. The National Treasury will facilitate the process of re-exporting the agreed items.

MEMBERS' OBSERVATIONS

Members observed that:

1. The fact that the agreement was fully funded by the USA was risky as there was no guarantee the friendly relations will last into the future. In this regard the knowledge and vulnerabilities discovered by the USA could expose the country.
2. Under executing agents and implementing agreements (Article III), the following ought to have been considered for inclusion: the State Law Office, Ministry of Agriculture, The National Intelligence Service (NIS), a representative of Faculties of Science in Kenyan universities, the Kenya Academy of Sciences, Kenyan experts in bioterrorism and the office of the Director of Public Prosecutions to deal with the issue of bio-terrorists being taken to court.
3. The agreement was initiated by Kenya after gaps were identified in a WHO survey which identified the need to build capacity in our laboratories with a deadline of 2017.
4. The US Department of Defense is well developed in terms of control of bio-hazards hence the USA government engaged it as the agency to collaborate with the Ministry of Health, Kenya on the need as expressed.

5. The Agreement would increase the capacity of Kenyan bio-hazard containment experts and the help equip the existing laboratories to meet international standards as expressed as per the WHO Standards.
6. The Ministry of Interior and Coordination of National Government had been involved as an implementation agency to capture the intelligence element of the implementation process.
7. There exists a Select Agents and Toxins List held by the Kenyan government that is the target for the assistance envisaged under Article I (3) (d) of the agreement.
8. The mechanism for engagement over Intellectual Property Rights envisaged under Article II (4) of the agreement shall be pre-determined prior to the implementation process.
9. There was need to have safeguards to endure the access to Kenyan facilities doesn't get used to the detriment of Kenya in future. Hence each implementing agency ought to play its role effectively to ensure the implementation process doesn't expose the country i.e. the assisting state doesn't exceed its mandate under the agreement.
10. The goods to be exported and imported under Article V shall be restricted to those used in the implementation of the agreement and personal belongings of personnel involved.
11. There is need to provide for an high level exchange program for human resource involved in the implementation to ensure that the Kenyan human resource benefits from the knowledge of their USA counterparts.

RESOLUTIONS

The Committee resolved that:

1. The Ministry of Health should provide the Select Agents and Toxins List to the Committee.
2. There should be a reservation to the Agreement with respect to Article V which shall provide that the exports shall not include microorganisms.

MIN.NO. DCH 261/2016:

ADJOURNMENT

There being no other business, the meeting was adjourned at 12.40 pm.

SIGNED:

**HON (DR.) RACHAEL NYAMAI, M.P.
CHAIRPERSON**

DATE: *30th August, 2016*



AGREEMENT

BETWEEN

**THE GOVERNMENT OF
THE REPUBLIC OF KENYA**

AND

**THE GOVERNMENT OF
THE UNITED STATES OF AMERICA**

**CONCERNING
COOPERATION IN THREAT REDUCTION
BIOLOGICAL ENGAGEMENT PROGRAMS**



PREAMBLE

This Agreement is by and between the Government of the Republic of Kenya and the Government of the United States of America, hereinafter referred to jointly as "the Parties" and singularly as the "Party";

Desiring to establish a cooperative program to facilitate mutually beneficial efforts to reduce biological threats of common concern;

Seeking to promote health security, including the Global Health Security Agenda, to reinforce the norms of safe and responsible conduct with respect to biological pathogens and toxins, and to obtain timely and accurate insight on current and emerging biological risks;

Intending to begin this cooperation with joint undertakings to address the dangers of naturally occurring and human-made or human-spread biological pathogens and toxins, to build capacity for disease surveillance, detection, diagnosis, and reporting, and to improve capacity against infectious diseases;

Proceeding consistently with the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, done at Washington, London, and Moscow on April 10, 1972, particularly Article X; the Treaty on the Non-Proliferation of Nuclear Weapons, done at Washington, London, and Moscow on July 1, 1968; and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, done at Paris on January 13, 1993;

Stressing the significance of United Nations Security Council Resolution 1540 of 2004, which expressed the Council's determination to facilitate effective responses to global threats of proliferation and terrorism and reaffirmed the need to combat these dangers to international peace and security;



Committed to the World Health Organization's International Health Regulations, 2005, which contribute to States' efforts to develop, strengthen, and maintain core national public health capacities to prevent, protect against, and control the spread of disease;

Anticipating the possible development of enhanced regional and global approaches to addressing shared safety and security; and

Determined to initiate the cooperative program rapidly and to establish terms that will help sustain the program and ensure its flexibility and responsiveness into the future;

NOW THEREFORE THE PARTIES HAVE AGREED AS FOLLOWS:

ARTICLE I: PURPOSE

1. The purpose of this cooperative program is to facilitate efforts to reduce the threat from naturally occurring diseases, biological attacks, or unintentional release of biological pathogens and toxins, and the risks posed by non-state actors of bioterrorism. The United States of America may provide, as agreed by the Parties, as appropriate and at no cost to the Government of the Republic of Kenya, assistance in support of efforts to identify; detect; predict; monitor; control; safeguard against; reduce; eliminate; prevent the proliferation of; ensure the safe storage and transport of; enhance the reporting of; improve mechanisms for response to; and strengthen research, training, and education related to potential biological threats.
2. The program shall consist of mutually agreed projects related to potential biological threats, including naturally occurring diseases, biological attacks, or unintentional releases of biological pathogens or toxins, and biological weapons-related pathogens and toxins, materials, processes, and knowledge.



3. For purposes of this Agreement:

- a. "goods and services" shall refer to all materials including biological materials and related information, equipment, supplies, commodities, facilities, services, funds, documents, records, technology, training, construction, property, personal property, or other assistance provided or used under this Agreement;
- b. "personnel" shall refer to the civilian and military personnel of both Parties;
- c. "contractors" shall refer to individuals and entities under contract or subcontract with the military and civilian agencies of both Parties, including its prime contractors and their employees, and first tier subcontractors and their employees; and
- d. "pathogens" shall refer to pathogens of security concern which include those agents and toxins included on the Select Agents and Toxins List as well as pathogens that cause emerging and re-emerging diseases capable of becoming threats to security through outbreaks, whether they be naturally occurring or caused by accidental or purposeful release.

ARTICLE II: SCOPE OF COOPERATION

1. The Parties shall cooperate in pursuing the goal of reducing the threat from naturally occurring diseases, biological attacks, or unintentional releases of biological pathogens and toxins, and the risks posed by non-state actors of bioterrorism. Areas of cooperation under this Agreement may include but are not limited to:
 - a. Implementation of a comprehensive, sustainable, and legally embedded national program for biosafety and biosecurity;



- b. Enhancement of the Government of the Republic of Kenya's capability to identify, consolidate, and secure collections of biological pathogens and toxins of security concern in order to prevent the sale, theft, diversion, or accidental release of biological pathogens and toxins;
- c. Enhancement of the Government of the Republic of Kenya's capability to rapidly and accurately survey, detect, diagnose, investigate alleged misuse of biological pathogens and toxins, and report biological terrorism and outbreaks from biological pathogens and toxins of security concern in accordance with international reporting requirements;
- d. Implementation of a functioning surveillance system within Kenya, capable of identifying and responding to potential events of concern to health security from biological pathogens and toxins;
- e. Implementation of policies and practices to minimize the spillover and spread, of emerging diseases;
- f. Supporting the implementation of an effective nationwide laboratory system within Kenya, capable of safe and accurate detection, identification, and characterization of biological pathogens and toxins of security concern, including both known and novel threats, that leverages regional resources and is commensurate with available technological capacities;
- g. Supporting collaborative research programs in biosurveillance, biosecurity, and biosafety;
- h. Supporting human resource development programs in biosafety and biosecurity; and
- i. Supporting training and awareness creation on biosafety and biosecurity issues.



The Parties shall agree upon implementing agreements that will identify specific project areas and requirements guided by the areas of cooperation specified above.

2. All activities undertaken pursuant to this Agreement shall be for peaceful purposes only and in compliance with the Treaty on the Non-Proliferation of Nuclear Weapons, done at Washington, London, and Moscow on July 1, 1968; the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, done at Washington, London, and Moscow on April 10, 1972; and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, done at Paris on January 13, 1993.
3. The Parties shall agree upon the disposition of any intellectual property discoveries or products resulting from activities undertaken pursuant to this Agreement.
4. The Parties shall agree, before implementation of cooperative biological research activities pursuant to this Agreement, on the following issues that may arise as a result of the activities undertaken pursuant to this Agreement:
 - a. Intellectual property rights;
 - b. Access and benefits sharing in relation to utilization of biological and genetic resources, traditional knowledge and folklore; and
 - c. Technology transfer.

ARTICLE III: EXECUTIVE AGENTS AND IMPLEMENTING AGREEMENTS

1. Each Party hereby designates an executive agent responsible for the coordination and facilitation of cooperative activities under this Agreement. The United States Department of Defence shall be the executive agent for the



Government of the United States of America, unless the Government of the United States of America otherwise notifies the Government of the Republic of Kenya. The Ministry of Health, in collaboration with the Ministry of Defence and the Ministry of Interior and Coordination of National Government, shall be the executive agent for the Government of the Republic of Kenya, unless the Government of the Republic of Kenya otherwise notifies the Government of the United States of America. Each Party may designate additional executive agents to this Agreement by written notification to the other Party.

2. Each Party, through its executive agents, may delegate rights and responsibilities under this Agreement to other agencies, departments, or units of its government or to other entities, as deemed appropriate, by written notification to the other Party.
3. The Parties or their executive agents may conclude agreements and arrangements to implement this Agreement.
4. The terms of this Agreement shall apply to any future implementing agreements and arrangements and to the activities undertaken pursuant thereto. In the event of any inconsistency between this Agreement and any implementing agreement or arrangement, the provisions of this Agreement shall prevail, unless otherwise specified.

ARTICLE IV: COSTS

Expenditures by the Government of the United States of America pursuant to this Agreement, including associated expenses and transportation costs, shall be subject to the availability of appropriated funds available to the U.S. executive agent or the responsible implementing agency for these purposes.



ARTICLE V: TAXATION, IMPORTS, AND EXPORTS

1. The Parties' personnel and other individuals conducting activities under this Agreement, who are in the other Party's country purposely for the implementation of this Agreement, shall be exempt from income tax of the host Party or any other deductions from their pay allowances and other emoluments and benefits (whether in cash or in kind) paid to them, obtained pursuant to activities under this Agreement. This paragraph shall not apply to citizens or residents of the Party in whose country the activities are performed.
2. Goods and services purchased locally or imported for direct use in the implementation of activities under this Agreement or exported after such implementation shall be exempt from all taxes, duties, and levies, including import duty, excise duty, Value Added Tax, Import Declaration Fee, and the Railway Development Levy.
3. If any licence or permit is necessary for the import or export of goods or services under this Agreement, the appropriate executive agent or other implementing agency for the receiving Party shall facilitate the obtaining of the necessary licences or permits in an expeditious manner. Fees for licences and permits imposed by the Government of the receiving Party on imports and exports for direct use in the implementation of the activities under this Agreement shall be borne by the receiving Party.

ARTICLE VI: LIABILITY

1. With respect to claims, other than contractual claims, the Parties shall not bring legal proceedings against each other or each other's personnel, contractors, and contractors' personnel for damage to each other's property, or death or injury to each other's personnel, in the territory of either party arising out of activities undertaken pursuant to this Agreement.
2. The Parties shall consult regarding claims by third parties against either Party, its personnel, contractors, and subcontractors for damage, loss, or destruction of



property, or injury or death to any individual arising out of activities under this Agreement. The provisions of this Article shall not prevent the Parties from providing compensation in accordance with their national laws.

ARTICLE VII: RESPECT OF DOMESTIC LAW

Civilian and military personnel of the Government of the United States of America who are present in Kenya in connection with this Agreement shall respect the laws of the Republic of Kenya at all times.

ARTICLE VIII: AUDITS AND EXAMINATIONS, ACCESS TO THE SITES

1. The Parties shall jointly monitor the implementation of this Agreement, to observe the progress of activities undertaken pursuant thereto, and to examine the use of goods and services provided under this Agreement. Such reviews shall occur at the site of the relevant work or activity, or, as agreed, at any other location. For the purpose of a project performed pursuant to this Agreement, the Parties shall have access to sites where the projects are undertaken or planned to be undertaken. A Party providing assistance under this Agreement shall have the right to inspect and audit all records and documents related to activities undertaken pursuant to this Agreement both during and for three years after the completion of each activity. The inspected Party shall prepare for and participate in such audits. For each audit and inspection visit, the inspecting Party shall provide written notification, to include the scope of the audit and the inspection, to the other party prior to the visit. For each audit and inspection visit, the inspected Party shall provide written confirmation for inspection or audit and may give input to the scope of the audit. A Party receiving assistance under this Agreement shall have the right to request an audit related to such assistance.



2. The Parties shall receive a copy of any official audit or inspection report prepared jointly, on activities undertaken under this Agreement. The Party that is subject to such an inspection shall provide a response to the report.
3. The Parties shall establish a committee to monitor the implementation of this Agreement.

ARTICLE IX: PROHIBITION ON TRANSFERS AND UNAUTHORIZED USE

1. No Party shall transfer title to, or possession or control over, goods or services provided under this Agreement or shall permit the use of such goods or services for purposes other than those for which they have been provided, without the consent of the other Party.
2. The Party in possession of goods and services provided pursuant to this Agreement shall take all reasonable measures to ensure security of the goods and services and shall protect them from theft or transfer to anyone other than someone designated by both Parties.
3. Each Party shall facilitate processing of goods and services related to this Agreement, within its territory, in order to ensure prompt delivery to their ultimate destinations.
4. The Parties shall agree on the modalities of transfer and sustainability of the goods and services pursuant to activities under the Agreement.

ARTICLE X: CONTRACTING

Any contract awarded by a Party for the acquisition of goods and services pursuant to this Agreement, including construction, shall be awarded to contractors, which may include U.S. and Kenyan contractors, and administered in accordance with that Party's acquisition and procurement laws and regulations.



ARTICLE XI: SETTLEMENT OF DISPUTES

Any differences concerning the interpretation or implementation of this Agreement shall be resolved solely through consultation or negotiation between the Parties.

ARTICLE XII: ENTRY INTO FORCE AND DURATION

1. This Agreement shall enter into force on the date of the last written notification in an exchange of notifications between the Parties by which the Parties notify each other, through diplomatic channels, of the completion of their internal legal procedures required for entry into force.
2. This Agreement shall remain in force, subject to Article XIII (2), for a period of five years from the date of its entry into force.
3. This Agreement may be renewed for an agreed period, upon mutual consultations and consent.

ARTICLE XIII: AMENDMENT AND TERMINATION

1. This Agreement may be amended by mutual written agreement of the Parties.
2. This Agreement may be terminated by either Party upon giving the other Party at least six (6) months written notification of intention to terminate.
3. Notwithstanding the termination of this Agreement, the obligations of both Parties with respect to the on-going activities shall continue until their completion subject to Article IV of this Agreement. Additionally, the obligations of the Parties, with respect to the goods and services provided under this Agreement, shall continue to apply, as specified in Article IX, unless otherwise agreed, and as specified in Articles VI and VIII.
4. Upon termination, the Parties shall consult regarding issues that arise in that context.



IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective Parties, have signed this Agreement in two originals, in English.

DONE at Nairobi, this 24th July, 2015.

FOR THE GOVERNMENT OF
THE REPUBLIC OF KENYA

FOR THE GOVERNMENT OF THE
UNITED STATES OF AMERICA

.....
MR. JAMES MACHARIA
CABINET SECRETARY FOR
HEALTH

.....
AMB. ROBERT F. GODEC
AMBASSADOR OF THE UNITED
STATES OF AMERICA TO KENYA



REPUBLIC OF KENYA

MINISTRY OF HEALTH

CABINET MEMORANDUM ON THE RATIFICATION OF THE AGREEMENT BETWEEN THE GOVERNMENT OF THE REPUBLIC OF KENYA AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA CONCERNING COOPERATION IN THREAT REDUCTION BIOLOGICAL ENGAGEMENT PROGRAMS

1.0 OBJECTIVE OF THE MEMORANDUM

The objective of the memorandum is to appraise the Cabinet on the Agreement between the Government of the Republic of Kenya and the Government of the United States of America concerning Cooperation in threat reduction biological engagement programs and to request the Cabinet to approve its ratification.

2.0 BACKGROUND OF THE SUBJECT MATTER

Biological threat agents are microorganisms or toxins that if accidentally or deliberately released can cause significant disease and death to people and animals, harm to the environment and/or devastate national economies. Examples include anthrax, pandemic influenza and Ebola virus.

Biological threats are associated with accidental release from a laboratory or deliberate release of a biological agent in an act of terrorism. Biological knowledge, tools and resources that can constitute biological threats are becoming more widely available around the world, including Kenya

Globally, there are growing concerns about potential misuse of biological knowledge and agents for terrorism purposes with the biomedical research and associated laboratories now also considered in security terms.

International agreements, including the Biological and Toxins Weapons Convention (BWC) and United Nations Security Council Resolutions 1540 of 2004 (UNSCR 1540), have asked countries to strengthen their implementation of biosecurity against biological threats.

3.0 ANALYSIS OF THE PROBLEM

Kenya possesses facilities including advanced human and animal health facilities that routinely work on microorganisms which are also considered biological threats.

In a survey conducted nationally in about 90 laboratories in 2014, half of the surveyed laboratories worked with pathogens which could be considered biological threats but most did not have measures and capabilities to mitigate the risks associated. These capabilities include infrastructural aspects, training and technological approaches that together are referred to as biological threat reduction.

Biological threat reduction is an approach that seeks to protect humans and the environment from exposure to and release of microorganisms or toxins that constitute biological threats. It also includes the containment under which infectious disease agents can be safely manipulated during research or public health activities that must occur in order to combat disease

Kenya and the US have been negotiating the Agreement on biological threat reduction for the past three years. The agreement was signed on 24th July 2015 during the state visit of the US President Barack Obama.

The development of the Agreement was necessitated by the need to have a cooperative program to facilitate efforts to reduce the threat from naturally occurring diseases, biological attacks, or unintentional release of biological pathogens and toxins, and the risks posed by non-state actors of bio-terrorism

The agreement is executed by The Ministry of Health in collaboration with the Ministry of Defense, and Ministry of Interior and Coordination of National Government for the Government of the Republic of Kenya and the United States Department of Defense for the Government of the United States of America.

Under the Agreement, the United States of America will provide, as appropriate and at no cost to the Government of the Republic of Kenya, assistance in support of biological threat reduction efforts.

REPUBLIC OF KENYA



**NATIONAL ASSEMBLY
ELEVENTH PARLIAMENT - FOURTH SESSION**

**In the Matter of consideration by the National Assembly of the
Ratification of the Agreement Between the Government of the
Republic of Kenya and the Government of the United States of
America concerning Cooperation in Threat Reduction Biological
Engagement Programs.**

SUBMISSION OF MEMORANDA

Article 118(1)(b) of the Constitution provides that, "Parliament shall facilitate public participation and involvement in the legislative and other business of Parliament and its Committees." Standing Order 127(3) states that, "the Departmental Committee to which a Bill is committed shall facilitate public participation and shall take into account views and recommendations of the public when the Committee makes its report to the House".

Further, section 8 of the Treaty Making and Ratification Act, 2012 provides for the consideration and Ratification of Treaties by Parliament. Subsection (3) states that, "the relevant Parliamentary Committee shall, during its consideration of the Treaty, ensure Public Participation in the ratification process in accordance with laid down parliamentary procedures".

The above mentioned Agreement has been submitted to the National Assembly and pursuant to section 8 of the Treaty Making and Ratification Act, 2012 is now committed to the **Departmental Committee on Health**.

Pursuant to Article 118(1)(b) of the Constitution and Section 8 of the Treaty Making and Ratification Act, 2012 the Committee invites interested members of the public to submit any representations they may have on the said Agreement. The representations may be forwarded to the **Clerk of the National Assembly, P.O Box 41842-00100, Nairobi**; hand-delivered to the **Office of the Clerk, Main Parliament Building, Nairobi**; or emailed to clerk@parliament.go.ke; to be received **on or before Thursday 11th August, 2016 at 5:00 pm.**

**JUSTIN BUNDI, CBS
CLERK OF NATIONAL ASSEMBLY**

...document and intend to submit a bid are required to submit their
...of receiving any further

