



The Africa Centres for Disease Control and Prevention



Contents

ACRONYMS	2
INTRODUCTION	3
SITUATIONAL ANALYSIS	5
THE REGIONAL BIOSAFETY AND BIOSECURITY INITIATIVE	7
PRIORITY AREAS	7
Enabling Priority Area 1.....	10
Enabling Priority Area 2.....	11
Operational Priority Area 3.....	12
Operational Priority Area 4.....	13
Operational Priority Area 5.....	14
Operational Priority Area 6.....	14
BUDGET AND PROPOSED ACTIVITIES	15
ANNEXES	17
Annex 1: Proposed Activities, Outputs and Deliverables.....	17
Annex 2: Detail 5 year implementation plan budget.....	20
Annex 3: Biosafety and Biosecurity Initiative Deliverables	20
Annex 4. Informational Monitoring and Evaluation Framework (for further development)	23

ACRONYMS

Africa Centres for Disease Control and Prevention	Africa CDC
African Federation of Biosafety Associations	AfBSA
African Union	AU
Biosafety and Biosecurity Initiative	BBI
Biological Safety Cabinets	BSCs
Biosafety and Biosecurity	BSBS
Biological Weapons Convention	BWC
Centers for Disease Control and Prevention	CDC
Global Health Security Agenda	GHSA
Global Health Security Index	GHSI
High Consequence Agents and Toxins	HCAT
International Federation of Biosafety Associations	IFBA
International Health Regulations	IHR
Joint External Evaluations	JEE
Member States	MS
Memorandum of Understanding	MoU
Monitoring and Evaluation	M&E
National Public Health Institutes	NPHI
National Reference Laboratories	NRL
Regional Collaborating Centres	RCCs
Regional Biosafety and Biosecurity Technical Working Group	RBB-TWG
Regional Centers of Excellence	COE
Terms of Reference	ToRs
United Nations Security Council Resolution	UNSCR
United Nations Food and Agriculture Organization	UN-FAO
World Health Organisation	WHO
World Organisation for Animal Health	OIE

FOREWORD

Africa CDC is a specialized technical institution of the African Union established to support public health initiatives of Member States and strengthen the capacity of their public health institutions to detect, prevent, control and respond quickly and effectively to disease threats. Among the five strategic areas of Africa CDC is Laboratory Systems and Networks whose goal is to strengthen clinical and public health laboratory systems and networks to assure quality and safety. Biosafety and Biosecurity is one of the program areas under Laboratory Systems and Networks strategic pillar.

The threat of a catastrophic biological event has been increasing, exacerbated by advancement in technology, increased global travel, terrorist interest in weapons of mass destruction and increased interactions between humans, animals and the environment. However, the capacity of Member States to prevent or respond effectively to such events is very weak. In response, the Africa CDC in collaboration with its regional and global partners launched the Biosafety and Biosecurity Initiative (BBI) whose goal is to strengthen the biosecurity and biosafety systems of African Union Member States to comply with the International Health Regulations.

To ensure a coordinated approach, Africa CDC developed a Biosafety and Biosecurity Five Year (2021-2025) Strategic plan. The Strategic Plan is based on the objectives of the Africa CDC BBI and the list of priorities identified during the regional consultations held between 2019-2021.

Through this Strategic Plan, Africa CDC invites Member States and development partners to contribute and participate in the implementation of the Biosafety and Biosecurity Initiative. Development partners can identify activities that align with their mandates in the region and proceed to implement these directly with Member States. Africa CDC will facilitate the engagement with countries while providing the overarching coordination role.

Africa CDC remains committed to strengthening biosafety and biosecurity capacity among Member States and invites collaborating partners to mobilize resources to support the initiative

Dr Yenew Kebede Tebeje

Head, Division of Laboratory Systems and Networks

Africa Centers for Diseases Control and Prevention

Africa Union Commission

INTRODUCTION

Taking into account the health challenges faced by the African continent and the necessity for an accountability framework for health security to protect citizens of the continent, the African Union (AU) Heads of States and Governments approved the establishment of the Africa Centres for Disease Control and Prevention (Africa CDC) through the Assembly decision AU/DEC.589 (XXVI) at the AU summit in January 2015 at Addis Ababa, Ethiopia. At its 26th Ordinary session in January 2016, the assembly adopted the statute of the Africa CDC and its framework of operations. Africa CDC was officially launched on the 31st January 2017. Article 3(6) of the Africa CDC statute states that “Africa CDC shall promote partnerships and collaborations among African Union Member States (AU MS) to address the emerging and endemic diseases and public health emergencies.” Article 5 of the statute also emphasized that “Africa CDC shall work with the World Health Organisation (WHO) and other multi-sectoral partners and external partners as well as the Africa CDC Regional Collaborating Centres (RCCs) to pursue the strategic objectives of the Centre.”

In developing on-going initiatives for strengthening biosafety and biosecurity, Africa CDC is furthering its mandate to harmonize disease control and prevention policies and promote the prevention and control of diseases by building capacity of public health institutions in AU MS. Biosafety involves the implementation of containment principles, technologies and practices to prevent unintentional exposure to biological agents. Biosecurity involves the protection, control and accountability of biological materials and information related to these materials and dual-use research, to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

To ensure a comprehensive and sustainable approach, One Health should be taken into account throughout the design and implementation of the initiative. Agriculture, the environment, and many other sectors all play a role in ensuring proper biosafety and biosecurity capacity that is extended across the continent. As such, it is critical to engage animal, plant, and human health communities – including laboratories and research facilities as well as develop robust plans to harmonize and coordinate implementation activities on biosafety and biosecurity.

Results of the WHO Joint External Evaluations (JEE) conducted between 2016 and 2019 and the 2019 Global Health Security Index (GHS Index) showed inadequacy of biosafety and biosecurity capacities across AU MS. In response, Africa CDC in 2019, supported by its regional and global partners, launched the Biosafety and Biosecurity Initiative (BBI) whose goal is to strengthen the biosecurity and biosafety systems of AU MS so that they can be capacitated to comply with the international requirements and regulations such as the International Health Regulations (IHR) (2005), the Biological Weapons Convention (BWC), and United Nations Security Council Resolution (UNSCR) 1540.¹ The initiative was motivated by the recognition that the risk of a catastrophic biological event continues to be magnified by global travel, urbanization, terrorist nefarious interest in weapons of mass destruction, and rapid advances in technology that could pose global risks through the development or manipulation of especially dangerous pathogens. Since 2019, the Africa CDC has been working with AU MS, in collaboration with its regional and global partners, to implement the BBI. To ensure a focused and coordinated implementation of the initiative, Africa CDC has developed a five (5) year strategic plan for the implementation of the BBI.

¹ United States Centers for Disease Control and Prevention, United States Defense Threat Reduction Agency (DTRA), The Nuclear Threat Initiative (NTI), Global Affairs Canada Weapons Threat Reduction Program, Open Philanthropy Project

SITUATIONAL ANALYSIS

The successful implementation of the initiative depends on several internal and external factors. Below is an analysis of some of these factors based on the first 2 years of implementation:

Table 1: Summary of the Situation Analysis

INTERNAL FACTORS	EXTERNAL FACTORS
<p style="text-align: center;">Strengths</p> <ul style="list-style-type: none"> • Convening power of Africa CDC as the technical arm of the AU • Awareness of the existence and work done by Africa CDC and Regional Collaboration Centers • Partner support (financial, technical) for biosafety and biosecurity • Existence of regional and global treaties, regulations on biosafety and biosecurity • Internationally accepted targets for a whole-of-government, national biosafety and biosecurity system 	<p style="text-align: center;">Opportunities</p> <ul style="list-style-type: none"> • Increased awareness for biosafety and biosecurity due to COVID-19 pandemic and Ebola Virus Disease • Expanding partner base specifically supporting biosafety and biosecurity initiative, including multilateral groupings and institutions • Existence of Regional Biosafety and Biosecurity TWG as well as Regional Collaboration Centres • Multiple completed gap analyses on Member State biosafety and biosecurity capabilities (JEE reports, GHS Index, etc.) that can guide implementation and better decision making • Legal mapping to support implementation of country-specific whole-of-government, national biosafety and biosecurity legal instruments
<p style="text-align: center;">Weaknesses</p> <ul style="list-style-type: none"> • Inadequate staffing and expertise dedicated to the rapidly expanding and implementation of the Biosafety and Biosecurity Initiative at Africa CDC • Slow approval and procurement processes at AU and AU MS • Limited legal instruments to address a whole-of-government approach to biosafety and biosecurity • Weak systems for enforcing implementation and sustainment of biosafety and biosecurity practices at national and facility level among AU MS • Weak health systems in AU MS • Lack of coordination among donors and sectors 	<p style="text-align: center;">Threats</p> <ul style="list-style-type: none"> • Limited funding to implement biosafety and biosecurity requirements Inadequate national and international financing of sustainable biosafety and biosecurity capacity • Political and social unrest • Emerging and re-emerging biological threats

This five (5) year strategic plan seeks to utilize existing strengths to address identified weaknesses. The opportunities will enhance the chances for successfully implementing this plan despite the identified threats. Being a technical arm of the AU, Africa CDC has the advantage of convening high-level political leaders from the continent where biosafety and biosecurity issues can be discussed and endorsed to pave way for national-level implementation. The BBI has been supported by regional and international partners both financially and availing of technical expertise. The existence of international treaties and regulations like the BWC, IHR (2005), UNSCR 1540 and the multi-country Global Health Security Agenda (GHS) provide widely accepted targets and standards in the areas of biosafety and biosecurity for countries to strive toward. Moreover, Africa CDC has

strong relationships with entities such as the United Nations Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE) that can be engaged to facilitate One Health approaches throughout the strategic plan implementation where appropriate.

In the last two years of implementing the initiative, there have been some challenges inherent with Africa CDC and AU MS that are worth noting. The rapid expansion of the initiative over the last two years constrained existing Africa CDC staffing, which currently only has two personnel dedicated to biosafety and biosecurity. An expansion of BBI staffing covering all 5 RRCs will match the rapid expansion and implementation of the initiative as well as ensure regional context is considered in planning and implementation. As a technical arm of the AU, there are inherent bureaucratic processes that are consistent with an expansive institution like the AU which can potentially slow implementation. Sustainable legislative structures in all AU MS will ease implementation of these proposed interventions. If they are not, interventions will be more challenging to implement within weak or non-sustainable governmental systems. Other weaknesses include weak health and regulatory systems in AU MS, lack of awareness, financing, and political support for biosafety and biosecurity - areas which this proposed plan seeks to address.

Despite these inherent and institutional weaknesses at Africa CDC and in AU MS, there are opportunities that the proposed plan will take advantage of, including the current awareness for biosafety and biosecurity due to the COVID-19 pandemic. The pandemic has created an opportunity for biosafety and biosecurity to be on the agenda at the highest political level. The biosafety and biosecurity partner base has also expanded and the launch of the BBI as a platform for a coordinated approach to strengthening biosafety and biosecurity has spurred additional interest and commitment. The multi-expert Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWG) established across the five (5) RCCs provide a platform for long-standing structures that coordinate implementation of the BBI using the One Health, whole-government approach.

Threats to the success of this initiative include limited funding directed towards biosafety and biosecurity by AU MS for sustainability, specialized expertise for biosafety and biosecurity across the region, and limited legal instruments to support the implementation of the initiative. There is also the continued threat of another pandemic or outbreak of natural, accidental, or deliberate origin due to emerging or re-emerging biological threats, which could derail efforts as resources are largely directed toward response.

THE REGIONAL BIOSAFETY AND BIOSECURITY INITIATIVE

The goal of the initiative is to strengthen the biosafety and biosecurity systems and capacities of AU MS to ensure compliance with international requirements and regulations such as the IHR (2005) and corresponding JEE requirements under the IHR Monitoring and Evaluation Framework, the BWC, UNSCR 1540, GHSA and others.

PRIORITY AREAS

The initiative is implemented across six (6) broad categories:

1. Enabling Africa CDC to form a strategic focus on biosafety and biosecurity and effectively implement and evaluate the impact of the BBI

2. Establishment and operationalization of five (5) multisectoral and multi-expert RBB-TWG and a continental TWG
3. Development of an AU-endorsed biosafety and biosecurity legal framework for use across AU MS
4. Establishment of a regulatory and certification framework for institutions handling High Consequence Agents and Toxins (HCAT)
5. Establishment of a regional training and certification program for biosafety and biosecurity experts
6. Strengthening AU MS biosafety and biosecurity capabilities, including through infrastructure support and training and capacity building of National Public Health Institutes (NPHI) and National Reference Laboratories (NRL), to prevent, detect and respond to accidental or deliberate biological events

STRATEGIC APPROACH

The six priority areas under the BBI include four operational priorities and two enabling efforts. The two enabling efforts consist of increasing Africa CDC capacity and developing continental and sub-regional TWGs and will need to be prioritized to successfully implement the four operational priorities. While details on each of the priority areas are included below, it is important to understand how they are all connected and will be managed by Africa CDC leadership.

Africa CDC, with an increase in human resource capacity at the headquarters level, will lead the establishment of multi-expert, multi-sectoral continental TWG. The continental TWG will provide strategic leadership and oversight in the development, implementation, evaluation, and sustainability of the BBI. The continental TWG will also oversee the implementation activities of the five RBB-TWGs, ensuring they are well-equipped to execute against priority actions developed during technical workshops and can leverage sub-regional biosafety and biosecurity tools and/or programs provided through the BBI to enhance national capabilities. An important component of the continental TWG is to coordinate partner contributions to the advancement of the BBI and measure the impact of the collective efforts on member state biosafety and biosecurity capacity development.

Each of the five sub-regional TWGs will be led by the RCCs, where applicable. The structure and functions of RCCs are available on <https://africacdc.org/regional-collaborating-centres/>. RCCs may also need additional human resource support to implement sub-regional activities, but needs will vary by sub-region. The RCCs will be responsible for convening the RBB-TWGs, ensuring the appropriate stakeholders are involved and that they are leading activities that will fill prioritized biosafety and biosecurity gaps within AU MS in a measurable way.

Specifically, it is important to recognize the contributions and current status of all five RCCs, which are in varying states of start-up and implementation. Currently, three (3) of the RCCs are fully operational (Central, Southern and Eastern RCCs all with limited staffing). Additional attention will need to be given to each RCC to ensure standardized operations and highly effective implementation. Each RCC will require a biosafety and biosecurity officer.

Through the continental TWG structure, Africa CDC will be responsible for overseeing the development and implementation of the four operational priorities. Given a large number of international partners in the biosafety and biosecurity space, Africa CDC should seek to leverage pre-existing tools, guidelines, and networks to accomplish the goals of the BBI. It will be important

to coordinate with partners already working with AU MS in this space to align efforts toward common goals to the great extent possible. This list of partners and related initiatives should include, but is not limited to the following:

- World Health Organization
- World Organisation for Animal Health
- Food and Agriculture Organization of the United Nations
- G-7 Global Partnership Against the Spread of Materials and Weapons of Mass Destruction
- Global Health Security Agenda Action Package Prevent 3 (APP-3)
- AU Peace and Security
- AU Inter-African Bureau for Animal Resources
- Global and Regional Development Banks
- Professional Associations
- Civil and Private Sector Partners

GOALS AND OUTCOMES FOR THE PROJECT

Short-Term

- Establish regional and continental structures to coordinate implementation of the BBI
- Develop a regional Biosafety and Biosecurity Legal Framework that guides development and implementation of national biosafety and biosecurity legal instruments in the Africa region

Medium-Term

- Capacitate the Africa CDC Headquarters and RCCs with human resources to support the implementation of the BBI
- Develop and implement regional training and certification programs for biosafety and biosecurity experts

Long-Term

- Establish self-sustaining Regional Centres of Excellence that coordinate training and capacity building of biosafety and biosecurity experts in collaboration with institutions of higher learning in the Africa region
- Strengthen National Public Health Institutes and National Reference Laboratory networks with capacity to prevent, detect and respond to accidental or deliberate biological events detected, including working in collaboration with plant and animal related entities and laboratories

Enabling Priority Area 1

Enabling Africa CDC to form a strategic focus on biosafety and biosecurity and effectively implement and evaluate the impact of the BBI

The rapid expansion of the BBI has put pressure on the existing staff within the laboratory division of Africa CDC. At the moment, there are only two dedicated staff (one senior and one technical staff) for BBI. In the long term, Africa CDC proposes the establishment of a staff complement with at least five staff members (two senior and three technical staff) specifically assigned to BBI to cover each of the five RCCs. The 2 senior staff will be responsible for the overall coordination of the initiative, working closely with the management team at Africa CDC Headquarters through the Head of Laboratory Division. The three (3) technical staff will work closely with AU MS, partners and regional experts in the implementation of activities at the MS level.

Additional funding will support the development and hosting of an online tool that measures the impact of Africa CDC, AU MS, and external partner investments and activities toward specific internationally-accepted targets for each operational priority.

Enabling Priority Area 2

Establishment and operationalization of five (5) multisectoral and multi-expert RBB-TWG and a continental TWG

Africa CDC will develop a continental TWG to coordinate the implementation of the BBI. The continental TWG will accelerate and optimize Biosafety and Biosecurity in the Africa Region through sharing best practices, elevating global biosafety and biosecurity as a national leaders'-level priority, and facilitating and tracking the development of a national capacity to comply with and adhere to the international, regional and national regulations that contribute to global health security. The TWG will be governed by agreed ToRs and will include broad representation from across sectors and from relevant international organizations and global initiatives. The continental TWG will meet in person, with the potential for additional virtual attendees, once per year.

The RBB-TWGs for each of the five Regions (Central, Eastern, Northern, Southern and Western Africa) constituted by officially nominated members from AU MS representing varied expertise from human, animal, plant and environmental health, security, customs, IHR Focal Persons, members of parliament, Ministry of Health legal officers, institutions of higher learning and occupational health specialists will be established and operationalized. The RBB-TWG, guided by agreed Terms of Reference (ToRs), will oversee the implementation of the BBI. They will serve as the permanent structure to review, approve and advocate for implementation of any interventions for BBI.

Africa CDC proposes that the RBB-TWG meet at least three (3) times virtually and once physically per year, with the option of additional meetings as needed.

The RBB-TWGs will identify regional priorities for biosafety and biosecurity to inform development of the strategic plans. The RBB-TWG will also focus on implementing sub-regionally relevant efforts that seek to advance the capacity of AU MS according to the priorities and proposals developed during technical working groups. RBB-TWGs will also prioritize regional activities that advance NPHI and NRL capacities such as joint pieces of training, laboratory twinning efforts, sharing of lessons learned, etc. The RBB-TWGs will also work with Africa CDC on sub-regional efforts

such as training and certification of centres of excellence. The RBB-TWGs will be responsible for reporting progress in alignment with the Africa CDC BBI impact measurement tool at designated intervals.

Operational Priority Area 3

Development of an AU-endorsed biosafety and biosecurity legal framework for use across AU Member States

In regional consultations led by Africa CDC, AU MS highlighted the lack, inadequacy, and fragmentation of legislation, regulation and policy frameworks relevant to biosecurity and biosafety as a key reason for the lack of prioritization and improvement of biosafety and biosecurity at national, sub-national, and regional levels.² In addition, AU MS indicated that other key challenges included the lack of translation of legal requirements into practice, ineffective coordination among stakeholders, insufficient political will and inadequate resources to move forward with development or revisions to additional legal instruments to support biosafety and biosecurity initiatives.

AU MS recommended that Africa CDC coordinate the development of a regional biosafety and biosecurity legal framework (BSBS Legal Framework). The BSBS Legal Framework serves two purposes: first, it may be used by a MS to guide review of existing legal instruments to more fully understand its existing legal capacity to support biosafety and biosecurity; second, the BSBS Legal Framework identifies ways that a MS legal instruments could be amended to increase support for biosafety and biosecurity oversight mechanisms. To ensure accountability, the framework allows for the establishment of an (or mandating an existing) agency to administer and enforce biosafety and biosecurity oversight systems at country level.

The framework has seven domains detailed below:

1. Authorization of the establishment of a lead entity/agency responsible for regulating and managing biosafety and biosecurity systems
2. Development of national standards for biosafety and biosecurity
3. Authority for biological risk assessment
4. Regulation of laboratory and facility requirements for handling high consequence agents and toxins
5. Education, training, and human resource development for all personnel who possess use, manipulate, store, transfer or destroy/incinerate high consequence agents and toxins
6. Transfer, storage, and disposal of high consequence agents and toxins x
7. Prohibition of all activities in the development, possession, and transfer of high consequence agents and toxins for the purpose of producing weapons of mass destruction.

Africa CDC proposes to develop an advocacy and communication strategy for socializing and gaining political commitment for the adoption and domestication of the legal framework at the AU and MS level. A regional and country-specific implementation guide will be developed to support the domestication process. The guide will cover areas including implementation guidance, how to conduct legal mapping, training and stakeholder engagement

2

Operational Priority Area 4

Establishment of a regulatory and certification framework for institutions handling High Consequence Agents and Toxins (HCAT)

To ensure accountability at national levels, Africa CDC proposes to develop a regulatory and certification framework for high containment facilities. Benchmarks and regional standards of biosafety and biosecurity based on international requirements for compliance by high-level containment institutions (human, animal, and plant health) will be developed with accompanying assessment tools/checklists for the evaluation of continued compliance. A certification framework based on recognition of incremental implementation and compliance to the national minimum standards will be used to award certification e.g., level 1-4 or star 0 to star 5. Training of AU MS on the minimum standards will be conducted through the established COE including a pool of assessors.

Operational Priority Area 5

Establishment of a regional training and certification program for biosafety and biosecurity experts

Based on the expressed and observed needs to be implemented through the BBI, Africa CDC proposes the development of regional training and certification programs in the following four (4) areas:

- (i) selection, installation, and certification of Biological Safety Cabinets (BSCs)
- (ii) biorisk management
- (iii) certification and maintenance of high containment facilities
- (iv) waste management.

The long-term vision is to build a mass of certified continental experts and promote biosafety and biosecurity as a profession. Key partners include the International Federation of Biosafety Associations (IFBA), African Federation of Biosafety Associations (AfBSA), national associations and institutions of higher learning.

Africa CDC proposes implementation of this regional training program through at least three (3) Regional Centers of Excellence (COE) and will develop criteria and ToRs, evaluate, select potential COE, establish Memorandum of Understanding (MoU) with host countries, capacitate the centres and develop a long-term sustainability plan for them.

Operational Priority Area 6

Strengthening AU Member State biosafety and biosecurity capabilities, including through infrastructure support and training and capacity building of National Public Health Institutes (NPHI) and National Reference Laboratories (NRL), to prevent, detect and respond to accidental or deliberate biological events

The COVID-19 pandemic highlighted the central role NPHI and NRL play in preparedness and response to any epidemic and pandemic, including those caused by a natural, accidental or deliberate release. Under this initiative, Africa CDC proposes to identify and strengthen biosafety and biosecurity aspects of NPHI and NRL to complement other capacity-building needs for surveillance, diagnostics and response.

A survey on the biosafety and biosecurity capacity needs for these facilities will be conducted following which infrastructures upgrading support and a training and capacity building program will be developed, reviewed, and endorsed by AU MS through the RBB-TWG and implemented. Training will be in collaboration with the established regional COE.

The support is expected to include (i) infrastructural improvements to meet the agreed minimum standards for biosafety and biosecurity (ii) biosafety and biosecurity equipment installation, certification and maintenance, including clean rooms (ii) training of personnel from NPHI, NRL and institutions handling high-risk pathogens in identified areas of biosafety and biosecurity.

As part of monitoring high-risk pathogens, Africa CDC will establish a surveillance program for selected high consequence agents and toxins to have a system to immediately pick such agents before they cause serious consequences to the public

BUDGET AND PROPOSED ACTIVITIES

The proposed budget will require **US\$18,416,000** of which the gap in funding is **US\$17,716,000** over 5 years (2021-2025). Below is a summary of the 5-year budget based on the seven outputs.

Annex 1 provides added detail for each priority area. This includes delineation of activities and sub-activities by year, as well as the associated costs. The annex also provides details on relevant outputs and deliverables by priority area.

Annex 2 provides a detailed breakdown five-year project plan budget

Annex 3 details the expected deliverables across the lifetime of the project, divided out by project goals. The relevant assumptions made are included. These will align with the Monitoring and Evaluation Framework contained in Annex 4.

Annex 4 outlines potential indicators that may be included in the monitoring and evaluation framework that will be used to track progress throughout the life of the program. The focus of the framework should be using internationally accepted indicators to measure the impact of the actions of the BBI, including those Africa CDC, MS, and partners execute. The framework should be available online and should be used by the BBI continental and regional TWGs to evaluate the progress of the Initiative.

Table 2: Five-year implementation budget summary

Output	Total Budget	Financial year					Available Funding	Financial Gap
		2021	2022	2023	2024	2025		
Biosafety and Biosecurity Legal Framework	\$ 736,000	\$ 138,000	\$ 204,000	\$ 154,000	\$ 120,000	\$ 120,000	\$ 106,000	\$ 630,000
Five Regional Biosafety and Biosecurity TWGs	\$ 2,180,000	\$440,000	\$450,000	\$450,000	\$ 420,000	\$420,000	\$0	\$2,180,000
A Regulatory and Certification of High Containment facilities	\$871,000	\$141,000	\$ 300,000	\$190,000	\$ 120,000	\$120,000	\$15,000	\$ 856,000
Regional Training and Certification program	\$ 4,349,000	\$369,000	\$1,070, 000	\$970,500	\$970,000	\$970,000	\$319,000	\$4,030,000
Trained and capacity building of NPHI and NRL	\$8,412,000	\$518,000	\$1,976,500	\$1,972,500	\$1,972,500	\$1,972,500	\$0	\$8,412,000
Human Resources	\$ 1,868,000	\$ 376,000	\$ 376,000	\$372,000	\$372,000	\$372,000	\$360,000	\$1,508,000
Total Budget	\$18,416,000	\$ 1,982,000	\$4,376,500,	\$4,108,500	\$3,974,500	\$3,974, 500	\$800,000	\$17,716,000

Annex 2: Detail 5 year implementation plan budget

See attached x-cell spreadsheet.

Annex 3: Biosafety and Biosecurity Initiative Deliverables

Deliverables	Means of Verification	Assumptions
<p>GOAL: Strengthen the biosafety and biosecurity capabilities of the Africa Region to prevent, detect and respond to events of public health concern and threats from high consequence agents and toxins</p> <p>PURPOSE: Strengthen Biosafety and Biosafety capabilities of the Africa CDC Secretariat, Africa CDC Regional Collaborating Centres, National Public Health Institutes and National Reference Laboratories, Animal and Plant Health laboratories</p>	<p>Project reports</p> <p>Meeting Reports, project reports</p> <p>Training Report, mission reports, project reports</p> <p>Consultancy reports, Project reports</p> <p>Consultancy reports,, Project reports</p> <p>Consultancy reports, Project reports</p>	<p>Existence of a National Public Health Institute in the MS</p> <p>Availability of nominated representatives. Relaxation of travel COVID-19 Lockdown restrictions</p> <p>Completion of training program, identification of facilities that require upgrades, availability of bio-safety equipment</p> <p>Identification of an institution with capacity to develop a certification program</p> <p>Identification of an institution with the capacity to develop a training program</p> <p>Identification of an institution with capacity to develop a program</p>

OUTPUTS:			
	Objectively Verifiable Outputs	Means of Verification	Assumptions
A Biosafety and Biosecurity Legal Framework for the Africa Region	A Communication and advocacy strategy	Meeting reports, Project Reports	Availability of Members to participate in meetings
	1 x Regional and 12 x National implementation roadmaps	Meeting reports, Project Reports	
	10 x Trainings on Legal Law, drafting of legal documents	Training workshop reports	Availability of Members to participate in meetings
5 Regional Biosafety and Biosecurity TWGs	15 x Virtual Meetings/year	Meeting Reports, project reports	Availability of nominated members to participate
	5 x Physical meetings/year	Meeting reports, Project Reports	
A Regulatory and Certification framework for institutions handling high consequence agents and toxins	List of gaps and priority actions required to improve compliance of MS with biosecurity and biosafety requirements based on WHO JEE	Report on priority gaps	
	1 x Regional minimum standards for biosafety and biosecurity	Consultancy reports, Meeting Reports	Identification of an institution with the capacity to develop a certification program
	1 x Assessment tool/checklist	Consultancy reports, Meeting Reports	Identification of an institution with the capacity to develop a certification program
	5 x Regional trainings on minimum standards	Training Report, project reports	Availability of participants
	5 x Regional trainings for assessors	Training Report, project reports	Availability of participants
	15 x Facility assessments for compliance to standards	Training Report, project reports	Availability of facilities to be assessed

OUTPUTS:			
Objectively Verifiable Outputs	Means of Verification	Assumptions	
Regional Certification Program for Biosafety and Biosecurity Professionals	1 x regional certification program	Consultancy report, Meeting Reports	Identification of an institution with capacity to develop training program
	12 x Trainings of experts at CoE	Training Report, project reports	Availability of participants
	12 x In-country competency evaluations and certifications	certification reports, Report, project reports	Availability of certifiers and participants
	10 x Biosafety and Biosecurity trainings	Training Report, project reports	Availability of participants
	1 x Criteria and ToRs for Regional Centres of Excellence (RCoE)	Project reports	
	5 x RCoE evaluation reports	Mission reports, project reports	Availability of countries to host RCoE
	3 x RCoE operational	RCoE update reports	Availability of countries to host RCoE
	1 x Rapid assessment report for NPHI and NRL biosafety and Biosecurity gaps	Meeting Reports	Member states responding to the survey
	1 x Training and capacity program addressing biosafety and biosecurity gaps for NPHI and NRL	Project reports	Identification of an institution with capacity to develop program
	5 x Regional trainings on biosafety and biosecurity derived from the program	Training reports	Availability of participants
	5 x Infrastructural upgrades/improvements to address biosafety and biosecurity requirements	Project reports	Availability of facilities to be upgraded
	5 x Installations of biosafety and biosecurity equipment	Project reports	Availability of facilities to accept the equipment
	1 x Bio-surveillance program for HCAT	Project reports	Availability of regional and national HCAT

Trained and capacitated staff from National Public Health Institutes in areas of prevention, detection and responding to events of public health concern and threats of high consequence agents and toxins

Annex 4. Informational Monitoring and Evaluation Framework (for further development)

Annex 4 will eventually contain a formal Monitoring and Evaluation Framework for BBI implementation. The information contained here as of 17 May 2021 is informational and provides an overview of possible data sources and validation that can be used to develop the final framework.

International Requirement(s) or Regulation(s)	Indicators	Purpose	Means of Validation
<p>World Health Organization Joint External Evaluation</p>	<ul style="list-style-type: none"> Existence of a national framework for pathogen biosafety and biosecurity, strain collections, containment laboratories, that includes identification and storage of national strain collections in a minimal number of facilities from all sectors. Existence of comprehensive oversight and monitoring systems. 	<ul style="list-style-type: none"> Implementation of a comprehensive, sustainable and legally embedded national oversight programme for biosafety and biosecurity, including the safe and secure use, storage, disposal and containment of pathogens found in laboratories and a minimal number of holdings across the country, and involving research, diagnostic and biotechnology facilities within all sectors. A cadre of biological risk management experts possessing the skillset to train others is established within their respective institutions. Strengthened, sustainable biological risk management best practices are in place using common educational materials. Rapid and culture-free diagnostics are promoted as a facet of biological risk management. Safe and compliant transport of infectious substances is also taken into account according to national and international regulations as appropriate. 	<ul style="list-style-type: none"> Documentation of dangerous pathogen collections housed in the country Establishment, enactment and enforcement of any relevant national legislation on biosafety and biosecurity Biosafety officers trained, receiving ongoing training and stationed at all laboratories that have the potential to handle dangerous pathogens and high risk experiments Policy document for biorisk or biosafety management in a facility is a written policy statement that is signed and reviewed annually OIE country PVS Evaluation mission report (also see section “Prevent – Zoonotic disease”) OIE country PVS Gap Analysis report (also see section “Prevent – Zoonotic disease”) OIE country PVS Laboratory mission report

International Requirement(s) or Regulation(s)	Indicators	Purpose	Means of Validation
<p>The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction</p>	<ul style="list-style-type: none"> Country signing or ratifying the Convention. 	<p>States Parties to the Biological Weapons Convention shall "never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:</p> <ol style="list-style-type: none"> microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict." 	<ul style="list-style-type: none"> Country signing or ratifying the Convention.
<p>Internationals Health Regulations (2005)</p> <p>Noting WHA provision on biosafety including:</p> <ul style="list-style-type: none"> World Health Assembly resolution 55.16 (2002) World Health Assembly resolution 58.3 (2005) World Health Assembly resolution 58.29 (2005) 	<ul style="list-style-type: none"> Select indicators and/or benchmarks related to the IHR Core Capacities (Core capacity 1: National legislation, policy and financing Core capacity 2: Coordination and National Focal Point (NFP) communications Core capacity 3: Surveillance Core capacity 4: Response Core capacity 5: Preparedness Core capacity 6: Risk communication Core capacity 7: Human resources Core capacity 8: Laboratory) 	<p>The purpose and scope of the IHR(2005) are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."</p>	<p>Applicable to all UN Member States, regardless of their membership in multilateral agreements.</p>

International Requirement(s) or Regulation(s)	United Nations Security Council Resolution 1540	Indicators	Purpose	Means of Validation
	<p>The resolution calls for the establishment of a national legal framework that should include the following elements:</p> <ul style="list-style-type: none"> • A system to account for and secure items in production, use, storage or transport; • Effective physical protection measures; • Effective border controls and law enforcement measures; and • Effective national export and trans-shipment controls. <p>The matrix for biological weapons and related materials identifies the following areas where domestic controls should be implemented and enforced:</p> <ul style="list-style-type: none"> • Measures to account for/secure production • Measures to account for/secure use • Measures to account for/secure storage • Measures to account for/secure transport • Regulations for physical protection of facilities/materials/transports • Licensing/registration of facilities/persons handling biological materials • Reliability check of personnel • Measures to account for/secure/physically protect means of delivery • Regulations for genetic engineering work • Other legislation/regulations related to safety and security of biological materials 	<p>In UNSCR Resolution 1540 (2004), the Security Council decided that all States shall refrain from providing any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes. The resolution requires all States to adopt and enforce appropriate laws to this effect as well as other effective measures to prevent the proliferation of these weapons and their means of delivery to non-State actors, in particular for terrorist purposes.</p>	<p>Applicable to all UN Member States, regardless of their membership in multilateral agreements.</p>	



www.au.int

