



DEVELOPMENT OF A NATIONAL BIOSAFETY AND BIOSECURITY STRATEGY



GUIDANCE TO AFRICAN UNION MEMBER STATES

A safe and secure Africa – the Africa we want

June 2022





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LIST OF ACRONYMS

Africa CDC	Africa Centres for Disease Control and Prevention
AU	African Union
BBI	Biosafety and Biosecurity Initiative
BWC	Biological Weapons Convention
GHS Index	Global Health Security Index
HCAT	High Consequence Agents and Toxins
IHR	International Health Regulations
JEE	Joint External Evaluation
MS	Member States
NBB-TWG	National Biosafety and Biosecurity Technical Working Group
RCC	Regional Collaborating Centres
RSME	Regional Submit Matter Experts
UNSCR	United Nations Security Council Resolution
WHO	World Health Organization

FOREWORD

Regional and global measurements matrices of the World Health Organization Joint External Evaluation and the Global Health Security Index, both confirmed the limited biosafety and biosecurity capacities of African Union Member States. The Africa Centres for Disease Control and Prevention (Africa CDC) Biosafety and Biosecurity Initiative launched in 2019 seek to strengthen the biosafety and biosecurity systems of Member States and enable them to comply with national, regional and global requirements for biosafety and biosecurity.

To esure a coordinated approach to implementation of interventions of the Initiative, Africa CDC developed the Africa CDC Biosafety and Biosecurity 5-Year Strategic Plan (2021-2025). Significant progress has already been made in achieving the set targets including drafting of a Regional Biosafety and Biosecurity Legal Framework that has passed the first stage of review by the African Union, launch of the Regional Training and Certification Program for Biosafety and Biosecurity Professionals, drafting of the Regulatory and Certification Framework for Institutions handling high risk pathogens among others.

The Initiative, has to date, targeted interventions meant to build systems and structures at regional level. These will in turn pave way for smoother implementation at national level using regionally agreed interventions. For example, the Regional Biosafety and Biosecurity Legal Framework defines the scope of legislation required for effective implementation. All what Member States will have to do is to domesticate the framework and align to national legislation.

At this stage, most of the regional interventions are at an advanced stage that allows cascading to national level implementation. To ensure there is a coordinated and atndardizzed approach to implementation at national level, Africa CDC has developed this guidance documents. The Guidance outlines priority areas and roadmap for cascading of regional initiatives to national level

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1.0 INTRODUCTION

Results of the World Health Organization's (WHO) Joint External Evaluations (JEE) conducted between 2016 and 2019 and the 2019 and 2021 Global Health Security Index (GHS Index) showed inadequacies of biosafety and biosecurity capacities across African Union (AU) Member States (MS). In response, the Africa Centres for Disease Control and Prevention (Africa CDC) in 2019, supported by 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 develop the capacities needed to comply with international requirements and instruments such as the International Health Regulations (IHR) (2005), the Biological Weapons Convention (BWC), and United Nations Security Council Resolution (UNSCR) 1540.

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

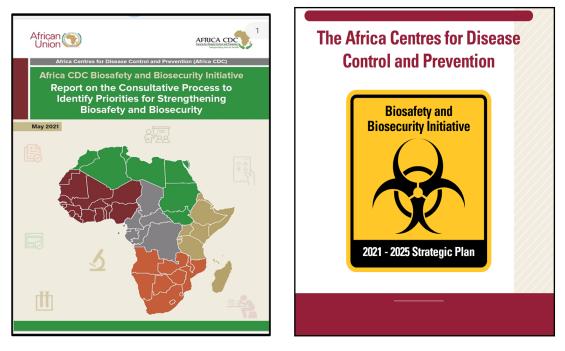


Figure 1: Regional Priorities Report and the Africa CDC Biosafety and Biosecurity 5Five Year Strategic Plan

In the first phase (2021-2025), the Strategic Plan prioritized five (5) areas of the BBI targeting at building regional structures and systems that Member States can use to strengthen their national biosafety and biosecurity systems. The regional to national approach ensures harmonization across the region and strengthen compliance to international requirements including the WHO JEE among others.

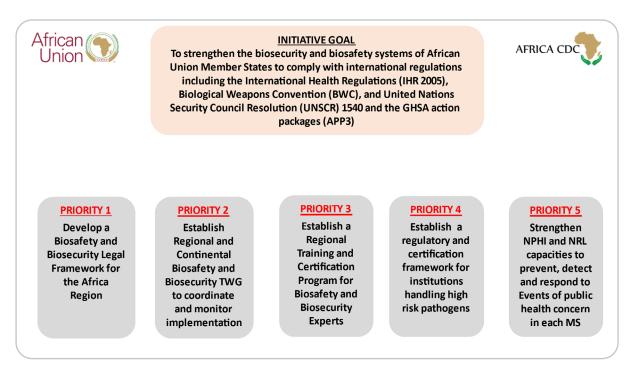


Figure 2: The five (5) priorities of the Africa CDC Biosafety and Biosecurity 5-Year Strategic Plan

2.0 RATIONALE

To date, the Africa CDC Biosafety and Biosecurity Initiative has been building systems and structures at Regional level. These will in turn pave way for smoother implementation at national level using regionally agreed interventions. For example, the Regulatory and Certification Framework for Institutions Handling High Risk Pathigens will set rregionally endorsed minimum standards for biosafey and biosecurity for high containment facilities. All what Member States will have to do is to adopt and adapt these as national standards and implement at national level.

As the regional interventions take shape, Member States can begin to cascade and implement these at national level. To ensure there is a coordinated and atndardizzed approach to implementation at national level, Africa CDC has developed this guidance document. The Guidance outlines priority areas and roadmap for cascading of regional initiatives to national level

3.0 IMPLEMENTATION AT NATIONAL LEVEL

The Regional Biosafety and Biosecurity Initiative seeks to build regional structures and systems that will enable Member States implement national biosafety and biosecurity systems. These include the development of a Regional Biosafety and Biosecurity Legislative Framework that will guide development of national legislation specific to biosafety and biosecurity, establishing a Regional Training and Certification Program for Biosafety and Biosecurity Professionals to ensure availability of adequate and appropriately trained and skilled human resources in biosafety and biosecurity, and establishment of Regulatory and Certification Framework for institutions handling high risk pathogens that will provide regionally accepted minimum standards for biosafety and biosecurity and a system for evaluating and certifying for compliance for Member States.

These regional structures and systems require domestication and implementation at national level. The following steps are recommended:

- 1. Establishment of a National Biosafety and Biosecurity Technical Working Group
- 2. Development of a National Biosafety and Biosecurity Strategic Plan
- 3. Development of a Monitoring and Evaluation Plan

3.1 STEP 1: Establishment of a National Biosafety and Biosecurity Technical Working Group

To ensure coordinate implementation of the biosafety and biosecurity program, a multisectoral National Biosafety and Biosecurity Technical Working Group (NBB-TWG) should be established. The NBB-TWG should be guided by agreed Terms of Reference and should consider the following composition: human health, animal health, environmental health, the International Health Regulations focal point office, representatives from the national legislature, Institution of Higher learning relating to health and life sciences laboratories, security, policy makers and political figures, civil society, customs, agriculture, security services, and others as they relate to country context. See Annex 1: Example of a NBB-TWG Terms of Reference

3.2 STEP 2: Development of a National Biosafety and Biosecurity Strategic Plan

To ensure appropriate prioritization and a coordinated approach to interventions, it is recommended that the NBB-TWG lead in developing a strategic plan by:

3.2.1 Conducting a Situation Analysis

Identify and analyze the internal and external factors based on previous, current, and future implementation. The strategic plan will utilize existing strengths to address identified weaknesses, use opportunities to enhance the chances for successful implementation despite the identified threats. Table below outlines the four key areas that must be identified as part of a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis. As part of your efforts, this should be completed in early stages with a diverse group of representatives from all relevant sectors and institutions (such as from the NBB-TWG).

Table 1: Summary of the Situation Analysis

INTERNAL FACTORS	EXTERNAL FACTORS
Strengths	Opportunities
Identify positive attributes within your system that are within your control.	Factors that are not within your full control but are likely to contribute to your success.
 What processes were used for interventions that have been successful What assets are available for use (skilled per- sonnel, infrastructure) 	• Are there current or upcoming events that may impact your system positively (e.g. current COVID-19 pandemic)
Weaknesses	Threats
What areas would need to be improved on that may negatively impact the success of your sys- tem	What are the factors not within your control that may impact negatively on your success?What factors require putting contingency
 Wat additional assets needed to be successful (personnel, finances, infrastructure) What processes need improvement 	plans if they occur.

3.2.2 Identify Priority Areas

Based on the situation analysis, broad priority areas are identified as follows:

- Strategic Goal: What is the desired end-state of the Initiative?
- Strategic Objectives: What are the key objectives that must be met to reach the goal?
- Interventions/Activities for each strategic goal: What specific steps and actions must be met to meet each objective?

Table 2 below provides an example of how to set up and identify these items.

Table 2: Example of strategic goal, objectives, and activities for the strategic plan

Strategic Goal: To strengthen the biosafety and biosecurity systems of Country X in order to have the capacity to comply with national, regional and international requirements including the WHO JEE

Objective 1: National Biosafety and Biosecurity Legislation is developed and implemented in the country by 2025

Activity 1	Conduct a situation analysis on existing legislation related to biosafety and biosecurity
Activity 2	Develop a roadmap for development and implementation of the National Biosafety and Biosecurity legislating
Activity 3	Conduct training on development of biosafety and biosecurity legislation
Activity 4	Draft biosafety and Biosecurity legislation bill and submit to legislature for review and approval
Activity 5	Conduct advocacy and communication for biosafety and biosecurity legisla- tion

Note: this table does not list all activities needed to reach the stated objective and goal. It is exemplary only.

3.2.3 Develop an Implementation Plan

Transform the strategic plan into yearly operational plan that covers the strategic plan period. The operational plan should include:

- Strategic Objective: What is the overall objective that must be accomplished this year and/ or reporting period?
- Strategic Objective Activities: What specific activities or actions must be taken to reach the overall annual objective?
- Cost for each activity: What is the estimated cost associated with each activity? This is particularly important for donor and national legislature engagement and should be backed up by a detailed costing analysis when possible.
- Timelines for Implementation: How long do I expect each activity to take?

See example in Table 3 below.

 Table 3: Example of a yearly implementation/operational plan for the Biosafety and Biosecurity

 Strategic Plan

Strategic Obje	ective 1: Begin de relevant pa		National Bio stakeholder					ollaborati	on with
Activities	Sub Activities	Unit Cost	Frequency	Total Budget	2022	2023	2024	2025	2026
Conduct a situation analysis on existing legislation related to biosafety and biosecurity	Workshop to conduct a desk review and situation analysis	\$15,000	1	\$15,000	\$15,000	\$0	\$0	\$0	\$0
Develop a roadmap for development and implementation of the National Biosafety and Biosecurity legislating	Workshop to conduct a desk review and situation analysis and develop a roadmap	\$15,000	1	\$15,000	\$15,000	\$0	\$0	\$0	\$0
Conduct training on development of biosafety and biosecurity legislation	Training Workshop on biosafety and Biosecurity legislation	\$15,000	5	\$75,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000
Draft biosafety and Biosecurity legislation bill	Workshops to draft bill	\$10,000	5	\$50,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000
and submit to legislature for review and approval	Advocacy and communication for the draft bill	\$5,000	10	\$50,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000
Total Objective 1				\$ 205,000	\$65,000	\$5,000	\$35,000	\$35,000	\$35,000

NOTE: When budgeting, ensure all sub-activities are considered e.g. For training – developing and printing training materials etc

3.3 STEP 3: Development of a Monitoring and Evaluation Plan

The Monitoring and Evaluation Framework must be used to track strategy implementation progress and should be developed concurrently with the Strategic Plan. The NBB-TWG should use the M&E Framework to review progress regularly (at minimum yearly).

PROGRAMME PROFILE		M&E INDICATORS		TADOLTO	Progress			
			BASELINE	TARGETS	2022	2023	2024	2025
SPI 1.	EFIFIC OBJECTIVES: Develop and implement a National Biosafety and Biosecurity Legislation by 2025	PROGRESS INDICATORS (OUTCOMES) A Draft Biosafety and Biosecurity Legislation submitted to legislature	0	Draft submitted to the legislation by December 2024				
2.	2. Establish and operationalize a	NBB-TWG established and functional	0	NBB-TWG established by July 2022				
	National Biosafety and Biosecurity TWG		0	Conduct 4 NBB-TWG meetings/year				
		S INPUT INDICATORS			Progress			
	INPUTS		BASELINE	TARGETS	2022	2023	2024	2025
PEI	PERSONNEL							
EQ	UIPMENTS/SUPPLIES							

Table 4: Example of a Monitoring and Evaluation Framework

FINANCES

4.0 NATIONAL ACTIVITIES TO SUPPORT REGIONAL INITIATIVE

The NBB-TWG should consider the following activities to support and compliment the Regional Biosafety and Biosecurity Initiative. In additional to national priorities as identified in the situation analysis and the findings from the WHO JEE, the proposed activities below should be included in the National Strategic Plan for Biosafety and Biosecurity.

 Table 5: Activities to be considered in the National Biosafety and Biosecurity Strategic plan

 in support of the regional Biosafety and Biosecurity Initiative

Priority Area as per Africa CDC Biosafety and Biosecurity 5-year Strategic Plan	Activities to Consider	Notes
Priority 1: Establishment of Biosafety and Biosecurity Technical Working Groups	Establish and operationalize a National Biosafety and Biosecurity Technical Working Group	The NBB-TWG must be multi-sectorial and multi- expert and its operations guided by agreed Terms of Reference. The NBB-TWG must report to the Regional Biosafety and Biosecurity TWG quarterly. Budget for: • Four meetings per year (at least two (2) of these could be virtual)
	Establishment of List of High Consequence Agents and Toxins (HCAT) list (priority pathogens)	The current legal framework in development require establishment of a HCAT List. Africa CDC can provide Technical Assistance on the process and tools. Budget for:
		 Four (4) 2-day workshops – participants should come from all sectors of one health: human health, animal health, agriculture, environmental, universities, security, customs, Govt IT, among others

Priority Area as per Africa CDC Biosafety and Biosecurity 5-year Strategic Plan	Activities to Consider	Notes
Priority 2: Biosafety and Biosecurity Legislative Framework	Legal Mapping and development of roadmap for domestication of the legislative framework	As preparation for domestication of the Biosafety and Biosecurity Legal Framework, Member States shall conduct legal mapping and use findings to develop a roadmap for domestication of Legal Framework which is under review by African Union. Budget for:
*We anticipate the Legal Framework to be available for use as approved document tentatively end of 2023		 Three (3) 2 - Day Workshops. One Health Participants. In the 2 days there will be training on legal frameworks development process and legal mapping and development of domestication plan Field Visits; 2 days - during legal mapping
		Africa CDC will support the Experts to facilitate the training and development of plans.
	Training on Biosafety and Biosecurity Legislation	The NBB-TWG should constitute a team to lead in the development of legislation. The selected team should undergo training and orientation on the process. Africa CDC will provide technical assistance in the training.
		Budget for:
		Three-day workshop
	Advocacy and communication for the Biosafety and Biosecurity legislation	The NBB-TWG should organize and conduct advocacy and communication for the Biosafety and Biosecurity legislation targeting all key stakeholders including civil society, communities, members of legislature. Budget for:
		 Development of Advocacy and communication materials Workshops/meetings with key stakeholders
	Draft a biosafety and Biosecurity legislation bill	The NBB-TWG should collaborate with government to organize and conduct
	and submit to legislature for review and approval	 Workshops to draft biosafety and Biosecurity legislation bill Workshop and subsequent activities for advocacy and communication for the draft bill
		Africa CDC will support experts to facilitate some of the workshops
Priority 3: Development of a Regional Training and Certification Program for Biosafety and Biosecurity Professionals	Certification of Trainees in the respective areas of specialization (Biorisk Management, BSc Maintenance, Biocontainment management and Waste Management)	Africa CDC will conduct Level 1 Training of participants from Member States. To procced to Level 2, participants will require to conduct in- country based improvement projects supervised by Regional Subject Matter Experts (RSME). The RSME will also conduct competency assessments of trainees and submit their portfolios to the Examination and Certification Council for certification for Level 2 and 3.
		Budget for:
		 Supporting trainees with implementation of improvement projects. This will include in-country travel to sites for practicals and competency assessment
		Africa CDC will support the RSME.

Priority Area as per Africa CDC Biosafety and Biosecurity 5-year Strategic Plan	Activities to Consider	Notes
Priority 4: Development of a Regulatory and Certification Framework for Institutions handling High Risk Pathogens.	Training of implementors in the Minimum Standards for biosafety and Biosecurity for institutions handling high risk pathogens	Regional Training of Trainers will be conducted for both implementors and assessors. Following that Member States is expected to support in-country trainings for to build local capacity. Africa CDC will support the experts to conduct the trainings.
*The regulatory and certification framework is expected to be available 3 rd Quarter of 2022	Training of Assessors to conduct in-country and regional evaluations of institutions that apply for certification	 Budget for One (1) 5-Day workshop for minimum standards One (1) 5-Day workshop for training assessors Assessments of in-country institutions (2 days per facility). Number of facilities will depend on institutions that handle high risk pathogens
Priority 5 : Strengthening National Public Health Institutes and National Reference Laboratories in Biosafety and Biosecurity	Training of Local Staff in biosafety and biosecurity	Africa CDC has developed and implemented a 7-Day Biosafety and Biosecurity Training of Trainers program. It is expected that countries, after the initial ToT, should conduct step down trainings. Budget for
		 One (1) 7-Day Training of Trainers workshop for up to maximum of 24 One Health Participants X (x) 5-day Step down trainings for Biosafety and biosecurity

5.0 CONCLUSION

The role of the NBB-TWG is central in coordinating interventions at national level. Hence, its composition must be as inclusive as possible to ensure all stakeholders are involved. Due consideration should be given to findings of the situation analysis as well as findings from the WHO JEE, National Action Plans for Health Security, and any other national or network assessments that are available.

The Strategic Plan is a source document upon which the NBB-TWG can use to mobilize funds from the Government as well as implementing partners. Africa CDC Biosafety and Biosecurity Initiative will continue to mobilize resources to support regional initiatives as well as provision of expertise that may not be available in-country (e.g., experts to facilitate trainings and workshops).

6.0 AFRICA CDC POINTS OF CONTACT

For any enquiries and further questions please contact:

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7.0 ANNEX

7.1 Example of a NBB-TWG Terms of Reference

National Biosafety and Biosecurity Technical Working Group

Terms of Reference

Background

[Insert country background information related to current status of Biosafety and Biosecurity]

Purpose

The main purpose of the National Biosafety and Biosecurity Technical Working Group (NBB-TWG) is to coordinate the implementation of the biosafety and biosecurity at national level. The NBB-TWG will mobilize the required political commitment from national leaders in prioritizing biosafety and biosecurity, lead sharing of best practices and development of cooperative efforts and guidance, and track the advancement of national capacities to comply with and adhere to the national, regional and international requirements that contribute to national and global health security.

Main Responsibilities

- Provide technical assistance in the development, implementation, and sustainability of biosafety and biosecurity initiatives towards compliance with national, regional and international requirements including the biosafety and biosecurity components of the International Health Regulations (2005) as measured by achievement of the Joint External Evaluation (JEE) targets¹ and Global Health Security Agenda resolutions.
- Identify strengths as well as remaining challenges and vulnerabilities in the country so as to explore strategies and solutions
- Provide guidance and technical assistance in the implementation of interventions to close identified biosafety and biosecurity gaps including development, implementation, and monitoring of National Action Plans for Health Security (NAPHS) ^{2,3,4,5}

¹ World Health Organization. (2018): Joint external evaluation tool: International Health Regulations (2005); 2nd ed. World Health Organization. https://apps.who.int/iris/handle/10665/259961

² World Health Organization. (2018): NAPHS for all: a 3 step strategic framework for national action plan for health security. World Health Organization. https://apps.who.int/iris/handle/10665/278961

³ World Health Organization. (2019): NAPHS for all: a country implementation guide for national action plan for health security (NAPHS): World Health Organization. https://apps.who.int/iris/handle/10665/312220

⁴ World Health Organization. (2019): WHO benchmarks for International Health Regulations (IHR) capacities. World Health Organization. https://apps.who.int/iris/handle/10665/311158

⁵ World Health Organization. (2019). Resource mapping and impact analysis on health security investment (REMAP): strategic partnership for IHR (2005) and health security (SPH). World Health Organization. https://

- Develop and implement national training and certification strategy in order to strengthen human resource capacity in biosafety and biosecurity
- Develop and implement of biosafety and biosecurity Standard Operating Procedures and other technical guidelines
- Promote multisectoral engagement across human and animal health, agriculture, security, defense, law enforcement, development assistance, international organizations such as WHO, OIE, FAO, Interpol and their partners, foreign affairs, research, and finance sectors, among others, following the One Health Approach in the implementation of biosafety and biosecurity⁶
- Facilitate dissemination and sharing of information, knowledge, and best practices on biosafety and biosecurity to policy makers, and other stakeholders
- Develop and track progress toward clear, measurable, and time-bound objectives of the National Biosafety and Biosecurity Strategy
- Track progress in achieving the national biosecurity and biosafety JEE targets

Composition/Membership

Membership shall be drawn from different sectors and stakeholders to ensure a multi-stakeholder and multi-expert inclusiveness

- Human Health
- Animal Health
- Environmental Health
- IHR focal point
- National Legislature
- Institution of Higher learning relating to health and life sciences laboratories
- Security
- Policy makers and political figures
- Civil Society
- Agriculture
- Implementing Partners

Secretariat

• Identify Lead Ministry to act as Secretariate

Coordination

- The TWG shall be chaired on a X-year rotational basis
- The Chair convenes meetings of the TWG
- The Secretariat shall organize meeting logistics and take and distribute minutes of meetings and other reports
- Methodology of working:
 - o Quarterly virtual meetings via video conferencing or teleconferencing
 - Annual physical progress review and planning meeting with 2 physical meetings in the first year of establishment
 - o Continuous communication via email and other knowledge sharing platforms

Quorum

apps.who.int/iris/handle/10665/329385

⁶ World Health Organization. (2020): Multisectoral preparedness coordination framework: best practices, case studies and key elements of advancing multisectoral coordination for health emergency preparedness and health security. World Health Organization. https://apps.who.int/iris/handle/10665/332220

A simple majority of all the members of the TWG of which any x members shall constitute a quorum for any meeting.

Agenda

The Meeting agenda will be prepared for every meeting by the secretariat and provided to the TWG members along with briefing material at least five (5) working days before the scheduled TWG meeting.

Decisions

Decisions will be made by consensus of the simple majority and where differences persist the various views can be expressed as opinions or options.

Accountability

The TWG will be reporting to xx.

Working Language

Working languages of the TWG shall be xx

Remuneration, Financing and Resources

Members of the TWG will not receive any remuneration for participation. [Insert local policy or attendance of official meetings]

Deliverables

Formal Meeting reports which will include an analysis of specific issues, recommendations, and proposals for actions by the TWG

Privacy and Confidentiality

TWG members will be expected to maintain confidentiality and operate in accordance with privacy principles when the group is dealing with sensitive matters. To support pro-active solutions and focus, confidential discussions will be undertaken without fear or favour.

It will be the responsibility of both the Chair and the members raising/discussing an issue to identify matters of a confidential nature.

Amendments

The TWG may amend these ToRs by a two-thirds majority.





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