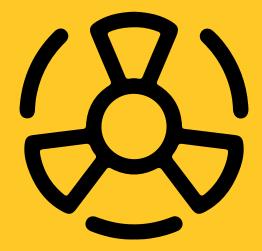




End-Term Evaluation of the Africa Centres for Disease Control and Prevention

Biosafety and Biosecurity



5-Year Strategic Plan (2021-2025)



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Abbreviations and Acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
ASLM	African Society for Laboratory Medicine
AU	African Union
BBI	Biosafety and Biosecurity Initiative
BSBS	Biosafety and Biosecurity
CEPI	Coalition for Epidemic Preparedness Innovations
DAC	Development Assistance Committee
DTRA	Defense Threat Reduction Agency
EQ	Evaluation Question
FGD	Focus Group Discussion
IDIs	In-depth Interview
IHR	International Health Regulations
JEE	Joint External Evaluation
KII	Key Informant Interview
M&E	Monitoring and Evaluation
MS	Member States
NPHI	National Public Health Institute
NRL	National Reference Laboratory
NTI	Nuclear Threat Initiative
OECD-DAC	Organisation for Economic Co-operation and Development – Development Assistance Committee
RBB-TWG	Regional Biosafety and Biosecurity Technical Working Group
RCC	Regional Coordinating Centre
RCoE	Regional Centre of Excellence
SP	Strategic Plan
SWOT	Strengths, Weaknesses, Opportunities and Threats
ToR	Terms of Reference
UNSCR	United Nations Security Council Resolution
US CDC	United States Centers for Disease Control and Prevention
WB	World Bank
WHO	World Health Organization

Definitions of Terms

Term	Definition
Biosafety	Measures and protocols to prevent unintentional exposure to pathogens and toxins, or their accidental release, especially in laboratories and high-containment facilities.
Biosecurity	Strategies and systems to prevent the theft, misuse, or intentional release of biological agents, ensuring control over access to sensitive biological materials.
Africa CDC	The Africa Centres for Disease Control and Prevention, a specialized agency of the African Union responsible for strengthening public health institutions' capacity to detect, prevent, control, and respond to disease threats.
RBB-TWGs	Regional Biosafety and Biosecurity Technical Working Groups established to provide multisectoral coordination, knowledge exchange, and strategic direction at the regional level.
Theory of Change (ToC)	A structured framework that outlines how specific activities are expected to lead to desired outcomes and impact through a causal results chain.
Reconstructed Intervention Logic	A consolidated model developed by the evaluator to represent how the BSBS Strategy's inputs, activities, outputs, outcomes, and impact are logically connected, serving as the analytical basis for evaluation.
Evaluation Questions (EQs)	Key guiding questions used to assess the implementation, effectiveness, and impact of the Strategic Plan. They align with evaluation criteria and thematic priorities.
Monitoring and Evaluation (M&E) Framework	A structured tool that tracks progress of the Strategic Plan through indicators at output, outcome, and impact levels, enabling performance measurement and learning.
OECD-DAC Criteriα	A set of internationally recognized evaluation criteria—effectiveness, impact, sustainability, relevance, efficiency, and coherence—used to assess development programs.
End-Term Evaluation	A comprehensive assessment conducted toward the end of the program implementation cycle to determine what was achieved, how, and why, and to generate lessons for future programming.
Mixed-Methods Approach	A research design combining both qualitative (e.g., interviews, focus groups) and quantitative (e.g., surveys, performance metrics) methods to ensure comprehensive and triangulated findings.
Sustainability	The likelihood that results, systems, or capacities established during the Strategic Plan will continue to function effectively after the program ends.
Impact	The long-term, strategic change or improvement that the program seeks to contribute to, typically beyond the direct control of the implementing institution.
Outcomes	The short-, medium- to long-term changes or effects resulting from program outputs. Outcomes reflect institutional capacity, systems strengthening, or behavioural change.
Outputs	The tangible products or services delivered through program activities, such as frameworks developed, trainings conducted, or institutions supported.
Activities	The specific actions and interventions carried out to implement the Strategic Plan, such as conducting training, developing legal tools, or convening regional consultations.

Foreword

The Africa Centres for Disease Control and Prevention (Africa CDC) has, since its establishment, remained steadfast in its mission to strengthen the capacity of African Union Member States to prevent, detect, and respond to public health threats. The COVID-19 pandemic underscored the urgent need to address persistent gaps in biosafety and biosecurity across the continent. In response, Africa CDC, in partnership with Member States and global partners, launched the first Biosafety and Biosecurity Strategic Plan (2021–2025) to provide a coherent framework for advancing health security and resilience in Africa.

This end-term evaluation report provides an important reflection on the achievements, challenges, and lessons of the past five years. It documents the progress made in strengthening institutional frameworks, building human resource capacity, and developing the legal and regulatory tools needed to manage high-consequence biological risks. Notable accomplishments include the establishment of five Regional Biosafety and Biosecurity Technical Working Groups, the adoption of an African Union—endorsed legal framework, the launch of a continental training and certification programme, and the piloting of certification systems for high-risk institutions. These achievements demonstrate the value of coordinated continental action and the collective commitment of Member States and partners to improving biosafety and biosecurity.

At the same time, the evaluation highlights areas where continued effort is required. Sustainability remains a critical challenge, with many Member States still reliant on external support and facing difficulties in institutionalizing biosafety and biosecurity within national systems. The limited integration of trained personnel, uneven progress in legal domestication, and gaps in infrastructure and equipment remind us that much work remains to be done to achieve the level of resilience Africa requires.

The findings and recommendations of this evaluation will serve as a foundation for the next strategic cycle (2026–2030). Building on the progress achieved, the new strategy must deepen national ownership, expand regional collaboration, and mobilize sustainable financing to secure the gains made and address emerging risks. Africa CDC remains committed to working closely with Member States, Regional Coordinating Centres, and partners to ensure that biosafety and biosecurity become integral pillars of Africa's health security architecture.

On behalf of the Africa CDC, I extend my appreciation to all Member States, regional bodies, development partners, and technical experts who contributed to the successful implementation of the 2021–2025 Strategy and to the conduct of this evaluation. The lessons documented here will guide our shared journey towards a safer, more secure, and more resilient Africa.

H.E Dr. Jean Kaseya Africa CDC Director General

Acknowledgements

Africa CDC expresses its sincere appreciation to all those who contributed to the successful completion of the end-term evaluation of the Biosafety and Biosecurity Strategy (2021–2025). This evaluation represents the collective effort of many individuals and institutions who shared their expertise, experiences, and time to ensure a comprehensive and credible assessment of the strategy's impact. Africa CDC gratefully acknowledges the active participation of stakeholders across African Union Member States, national institutions, and partner organizations. Government officials, representatives of National Public Health Institutes, National Reference Laboratories, ministries of health, agriculture, environment, and security, as well as members of Regional Biosafety and Biosecurity Technical Working Groups, generously shared their perspectives and experiences. Their contributions provided valuable context and practical insights that enriched the evaluation findings.

We also recognize the important role played by continental and regional partners. Teams from Africa CDC headquarters and ASLM, together with participants in the Regional Consultative Meetings, provided feedback, reviewed draft findings, and offered substantive inputs that greatly enhanced the quality and relevance of this report.

The Africa CDC extends its gratitude to development and technical partners—including Global Affairs Canada, the US CDC, the Defence Threat Reduction Agency, the Nuclear Threat Initiative, the World Bank, and others—for their longstanding support to BSBS strengthening in Africa. Their continued collaboration and financial investment have been indispensable to the progress achieved under the 2021–2025 Strategy.

Finally, Africa CDC expresses deep appreciation to all individuals and institutions—whether directly mentioned or not—whose commitment, expertise, and dedication contributed to the successful conduct of this evaluation. The lessons and insights captured here reflect the collective efforts of our Member States, partners, and technical experts, and will serve as a foundation for advancing biosafety and biosecurity across Africa in the years ahead.

Dr. Yenew Kebede Tebeje

Acting Director, Centre for Laboratory Diagnostics and Systems, Africa CDC

Executive Summary

The Africa CDC Biosafety and Biosecurity Strategic Plan (2021–2025) was developed to strengthen Africa's capacity to prevent, detect, and manage biological threats by building resilient biosafety and biosecurity (BSBS) systems at national, regional, and continental levels. The strategy was a response to longstanding gaps in investment and coordination, reflected in the 2019 and 2021 Global Health Security Index where sub-Saharan Africa scored an average of only 19.8 out of 100, and in World Health Organization (WHO) Joint External Evaluations (JEE) which showed that nearly three-quarters of African countries had little or no biosafety and biosecurity capacity. Implemented with the support of Global Affairs Canada, United States Centres for Disease Control and Prevention (US CDC), the Defence Threat Reduction Agency (DTRA), the Nuclear Threat Initiative (NTI Bio), the World Bank, and the African Society for Laboratory Medicine (ASLM), the strategy was structured around six priority areas: strengthening Africa CDC's internal capacity, establishing and operationalizing Regional Biosafety and Biosecurity Technical Working Groups, developing a continental African Union (AU)-endorsed legal framework, creating a certification framework for institutions handling high-risk pathogens, implementing a regional training and certification program, and supporting Member States to strengthen their BSBS infrastructure and institutional capacity.

The end-term evaluation, conducted between April and June 2025, assessed the effectiveness, efficiency, sustainability, and impact of the strategy while drawing lessons to inform the next cycle (2026–2030). It adopted a participatory mixed-methods approach guided by Organisation for Economic Co-operation and Development – Development Assistance Committee (OECD-DAC) criteria and engaged 297 respondents across 53 of the 55 (96%) AU Member States. Data collection comprised 199 survey responses, 42 key informant interviews, 29 in-depth interviews, and seven focus group discussions, complemented by desk reviews, benchmarking and SWOT analysis, and anchored in a 69-indicator evaluation matrix.

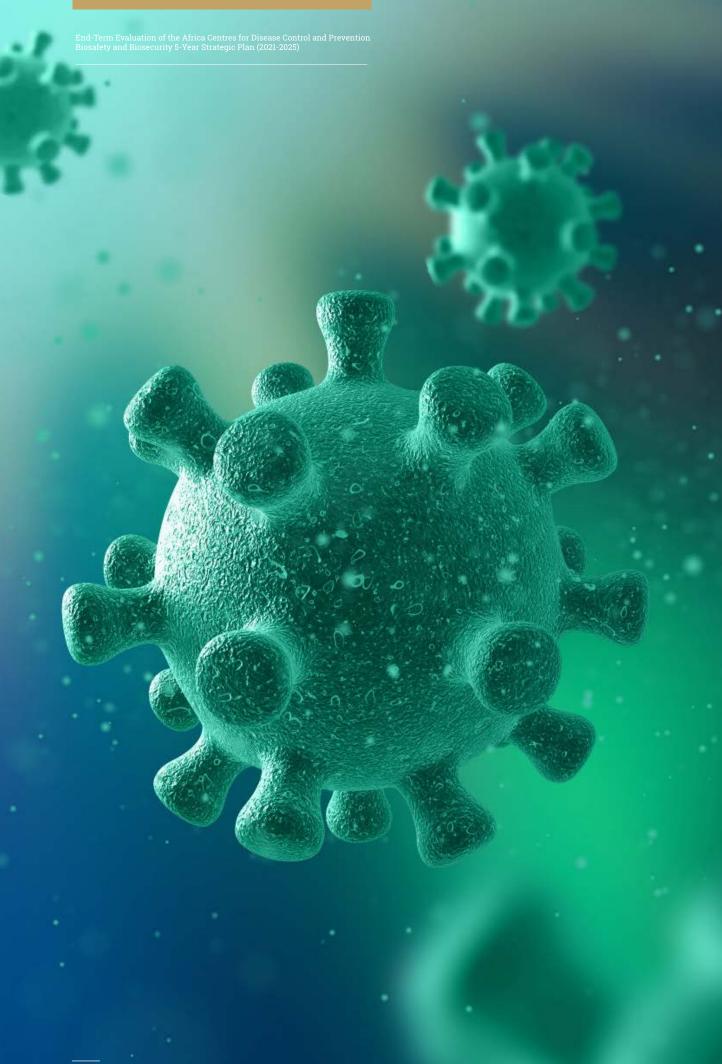
Findings show that strategic coordination and governance were significantly enhanced, with Africa CDC institutionalizing BSBS leadership through the creation of a dedicated unit, although staffing reached only 40% of the intended target. Despite these limitations, Africa CDC developed essential technical tools, elevated visibility for BSBS across the continent, and provided catalytic support to Member States. All five Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) were successfully established and operational, convening 100 meetings that facilitated multisectoral engagement, peer learning, and alignment of national actions. The AU-endorsed legal framework was developed, validated, and formally adopted by Heads of State, while legal mapping and gap analyses were completed in eight Member States. Seven countries developed national roadmaps and trained legal drafters, with early domestication underway in countries such as Zimbabwe and Botswana, although progress has been slowed by political and institutional constraints.

The certification framework for institutions handling high-consequence pathogens and toxins resulted in certification of four institutions, 45 trained assessors, and 83 implementors. While these achievements represent an important foundation, the pace of implementation was slower than anticipated due to technical and operational challenges. Capacity development efforts were more advanced: a regional training and certification programme was launched, with 315 professionals completing Level 1 certification, 45 beginning Level 2, and more than 50 subject matter experts trained across the regions. Step-down trainings were conducted in multiple Member States, but the integration of trained personnel into national human resource systems and sustained mentorship remain weak. Africa CDC also provided targeted support to strengthen institutional capacities in

National Public Health Institutes and National Reference Laboratories, though infrastructure upgrades and procurement of essential equipment were uneven and largely dependent on external support. Overall, the strategy succeeded in elevating biosafety and biosecurity as a continental priority, advancing regional coordination, catalysing legal and technical reforms, and developing tools and human resources that will serve as a foundation for future progress. At the same time, its reliance on donor financing, limited staffing at the continental level, and weak institutionalization at national levels threaten sustainability. The evaluation concludes that the RBB-TWG model, the AU legal framework, and the regional training program represent durable and high-value achievements, but their long-term impact will depend on embedding biosafety and biosecurity into national budgets, mandates, and planning frameworks.

Looking forward, the next strategic cycle must consolidate these gains by accelerating legal domestication, scaling up certification systems for high-risk institutions, and expanding mentorship and career pathways for biosafety and biosecurity professionals. Greater emphasis is required on national ownership through predictable government budget lines, integration of biosafety and biosecurity into the mandates of NPHIs and other institutions, and strengthened engagement of non-state actors including academia, private laboratories, and civil society. Sustained partnerships and diversified resource mobilization will be critical to reduce dependency on external funding.

In conclusion, the 2021–2025 Biosafety and Biosecurity Strategy marked an important milestone for Africa, laying the groundwork for a safer and more resilient continent. By establishing structures, tools, and networks for regional cooperation, it positioned biosafety and biosecurity as an integral part of Africa's health security agenda. The coming strategic cycle provides an opportunity to embed these achievements into national and regional systems, ensuring their sustainability and long-term contribution to safeguarding public health and security across Africa.



1 Background

Biological risks — whether accidental, natural, or deliberate — pose significant threats to public health, national security, and economic stability. In Africa, persistent gaps in biosafety and biosecurity (BSBS) systems have long been recognized as critical weaknesses within national and regional health security architecture. Assessments such as the World Health Organization's Joint External Evaluation (JEE)¹ and the Global Health Security Index (GHS Index)² have consistently highlighted limited BSBS capacity across much of the continent, with sub-Saharan Africa scoring particularly low on prevention and preparedness indicators.

In response to these challenges, the Africa Centres for Disease Control and Prevention (Africa CDC), in collaboration with African Union (AU) Member States and technical partners, launched the Biosafety and Biosecurity Initiative (BBI) and developed the continent's first 5-Year Biosafety and Biosecurity Strategy (2021–2025)³. The strategy aimed to strengthen institutional and technical capacity to prevent, detect, and respond to biological threats through a regionalized, multisectoral, and One Health approach.

The Strategy was organized around six Priority Areas — two enabling and four operational — designed to provide a coordinated foundation for implementation across Member States:

Enabling Priority Area 1

 Strengthening Africa CDC's internal capacity to lead, implement, and evaluate the BSBS initiative.

Enabling Priority Area 2

• Establishing and operationalizing five multisectoral and multi-expert Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) and a continental TWG to support regional coordination, knowledge exchange, and policy alignment.

Operational Priority Area 3

• Developing an AU-endorsed biosafety and biosecurity legal framework to guide Member States in establishing or updating national legislation aligned with international obligations such as the IHR (2005), BWC, and UNSCR 1540.

¹ The Joint External Evaluation (JEE) is a voluntary, collaborative assessment tool coordinated by the World Health Organization (WHO) to evaluate a country's capacity to prevent, detect, and respond to public health threats under the International Health Regulations (IHR 2005). It includes biosafety and biosecurity as core technical areas.

² The Global Health Security Index (GHS Index) is a comparative assessment of health security capabilities in 195 countries, developed by the Nuclear Threat Initiative (NTI), the Johns Hopkins Center for Health Security, and the Economist Impact. It evaluates national capacity to prevent, detect, and respond to health threats, including biosafety and biosecurity readiness.

³ The Africa CDC Biosafety and Biosecurity Strategy (2021–2025) is a five-year continental strategy developed to strengthen institutional, legal, technical, and human resource capacities across African Union Member States. It aims to enhance biosafety and biosecurity systems aligned with international obligations, including the IHR (2005), BWC, and UNSCR 1540.

Operational Priority Area 4

 Establishing a regulatory and certification framework for institutions handling High Consequence Agents and Toxins (HCAT), including assessment tools, minimum standards, and regional certification systems.

Operational Priority Area 5

• Implementing a regional training and certification program for biosafety and biosecurity professionals, delivered through Regional Centres of Excellence to build individual competencies and institutional capacity.

Operational Priority Area 6

 Strengthening Member State biosafety and biosecurity capabilities through infrastructure upgrades, technical assistance, and the training and deployment of national experts, particularly within National Public Health Institutes (NPHIs) and National Reference Laboratories (NRLs).

To guide implementation and enable performance tracking, Africa CDC developed a Monitoring and Evaluation (M&E) framework and a logical framework, later consolidated into a reconstructed intervention logic for this evaluation. This logic outlines a results chain connecting inputs and activities to outputs, outcomes, and long-term impact. The overall intended impact of the Strategic Plan was for AU Member States to demonstrate strengthened and sustainable BSBS systems aligned with global health security frameworks. Key assumptions included the availability of technical expertise, national commitment to legal and regulatory reform, and regional cooperation through Africa CDC and its five Regional Coordinating Centres (RCCs).

This end-term evaluation assesses the extent to which the BSBS Strategy achieved its intended results across the six Priority Areas. It draws on a reconstructed intervention logic, an evaluation matrix aligned to 10 core evaluation questions (EQs), and data collected through key informant interviews, in-depth interviews, focus group discussions, and an online survey. The evaluation aims to determine strategic achievement, identify lessons learned and implementation challenges, and generate forward-looking recommendations to inform the next BSBS Strategy (2026–2030).

Evaluation Objectives and Scope

2.1 Evaluation objectives

2.1.2 Main Evaluation Goal

The overall aim of the evaluation was to assess the overall achievement, effectiveness, implementation, and impact of the BSBS 5-Year Strategy (2021–2025), in order to generate lessons learned, identify challenges, and provide strategic recommendations to inform the design and theory of change of the next strategy (2026–2030)

2.1.3 Specific Objectives

The evaluation assessed the following specific objectives

Assessing the extent to which the BSBS Strategic Plan achieved its intended outcomes and strategic objectives

Evaluating the effectiveness of program interventions, including capacity-building, coordination mechanisms, and technical support

Examining the quality and efficiency of implementation at the continental, regional, and national levels

Assessing the broader impact of the strategy on biosafety and biosecurity systems across Africa CDC and Member States

Assessing the extent to which the outcomes and capacities developed through the Biosafety and Biosecurity Strategic Plan are likely to be sustained beyond the implementation period

Identifying key challenges and enabling factors that influenced the implementation and outcomes of the Strategic Plan

Generating evidence-based lessons and recommendations to guide the development and theory of change of the BSBS (2026-2030) Strategic Plan

2.2 Scope of the Evaluation

The main objective of the evaluation was to undertake end of BSBS 5 - Year Strategy (2021 - 2025) evaluation. This end-term evaluation covered the implementation of the BSBS 5-Year Strategic Plan from 2021 to 2025. It focused on activities and results achieved at the continental, regional, and national levels across the AU Member States, with a specific emphasis on the contributions of Africa CDC, its five Regional Coordinating Centres (RCCs), national implementing partners such as National Public Health Institutes (NPHIs) and National Reference Laboratories (NRL) and development and implementing partners.

The evaluation assessed the effectiveness, implementation quality, and impact of the strategy in strengthening BSBS systems. It also addressed cross-cutting issues such as coordination, legal framework development, capacity building, and institutional sustainability. Key evaluation issues included overall achievement, challenges, lessons learned, and recommendations to inform the development of the next BSBS Strategic Plan (2026-2030).

The evaluation also included an assessment of the likelihood that key results and institutional systems developed under the BSBS Strategy will be sustained over time. This focus helped to generate forward-looking recommendations and contributed to the formulation of the theory of change and design elements of the next strategy cycle (2026–2030).

Reconstructed InterventionLogic of the (2021-2025) BSBSStrategy

3.1 Introduction

The BSBS 5-Year Strategic Plan (2021–2025) was supported by an M&E framework and Logical Framework that outlined key results areas, outputs, and performance indicators. Drawing upon these foundational documents, a reconstructed intervention logic was developed to consolidate the results chain into a single, coherent model. This reconstructed logic provided a clear pathway from activities to outputs; short, medium and long-term outcomes, and ultimate impact, and served as the analytical backbone of the evaluation matrix by enabling a clearer alignment with the evaluation questions, judgment criteria, and indicators. Also, it served as a foundation for future learning through providing a clear and evaluable model that supported the refinement or redesign of the Theory of Change for the (2026-2030) strategy. By clarifying the causal pathways and key assumptions, it helped identify areas where the Theory of Change may need to be adjusted based on implementation experience, challenges, and emerging needs. Therefore, it supported evidence-based planning and alignment for the next phase of BSBS strengthening efforts.

3.2 The Intervention Logic Diagram

The diagram in Figure 1 visually represents the reconstructed intervention logic of the 2021-2025 BSBS Strategic Plan. It illustrates the logical sequence from inputs and activities to outputs, outcomes, and the intended impact, highlighting the cause-and-effect relationships that underpin the programme's design. This served as a foundation for the evaluation, guiding the assessment of effectiveness, impact and sustainability. See Annex 1 for the detailed reconstructed Intervention Logic of the BSBS Strategic Plan.

Inputs:

Planned inputs

- Financial resources
- Human Resources
- Technical expertise
- Biosafety and Biosafety equipment
- Assessment tools and

benchmarks

- Skilled trainers and assessors
- Training materials and logistical support
- Institutional support and coordination

Assumptions:

- No disruption due to natural disasters oroutbreaks/ pandemics
- Financial resources are disbursed on time
- Skilled human resources are available and recruited

Activities:

- 1. Team of Experts develop Draft 0 of BSBS Legal Framework
- Consultative meetings with MS to review -Advocacy meetings
- Development and Implementation of roadmap
- 2. Establish and operationalize RBB-TWG
- Develop and implement a
 Regulatory and Certification
 framework for institutions

handling HCAT

- Develop and implement a regional training and certification program for BSBS Experts
- Establish RCoEs
- 5. Develop and implement a 5 Year regional training and capacity building program
- 6. Hiring of Staff for BSBS

Assumptions:

- Availability of nominated representatives and technical experts
- Adequate funding

Outputs:

- A Biosafety and Biosecurity Lega Framework for the Africa Region
- Five Regional BSBS Technical Working Groups
- A Regulatory and Certification framework for institutions handling high consequence agents and toxins
- Regional Training and Certification program for BSBS Experts
- Trained and capacitated staff from NPHI and NRL in areas o prevention, detection and responding to events of public health concern and threats of high consequence pathogens
- 6. Support Human Resources at Africa CDC for BSBS

Assumptions:

- Availability of Member
 States willing and have the capacity to host Centres of Excellence
- Availability of members to participate in meetings

Outcomes:

Short-Term

- Functional regional coordination (RBB-TWGs)
- A regional BSBS Legal Framework in place

Medium-Term

- Functional technical support teams at Africa CDC & RCCS
- Trained & skilled workforce
- Improved compliance with

standards

- Improved facility capacity
- Roadmaps & domestication of BSBS Legal Framework

Long-term

- Fully operational and self-sustaining RCoEs
- Strengthened NPHIs and NRL networks

Assumption:

 Political commitment exists at the national level to align with the AU framework

Impact:

AU MS demonstrate strengthened and sustainable BSBS systems and comply with international requirements and regulations such as the IHR (2005) JEE.

Assumption: MS conduct JEE

Figure 1: Reconstructed Intervention Logic of the BSBS Strategic Plan (2021–2025)

3.3 Levels of the Reconstructed Intervention Logic

The reconstructed intervention logic captures the strategic design of the BSBS Strategy and reflects how Africa CDC, its Regional Coordinating Centres (RCCs), Member States, and technical partners worked together to strengthen BSBS systems across the continent. It also highlights key assumptions and contextual factors influencing results.



Activities refer to the operational and technical interventions implemented under the Strategic Plan — including the development of tools and standards, delivery of regional training, legal framework consultations, and coordination support.



Outcomes represent the intermediate changes expected to emerge from these outputs, including improvements in institutional capacity, legal alignment, coordination mechanisms, and practical application of BSBS practices. These were conceptualized to occur over short-, medium-, and long-term timeframes.



Outputs are the immediate, tangible results of those activities — such as the establishment of Technical Working Groups, adoption of minimum standards, trained personnel, and assessed institutions.



Impact reflects the BSBS Strategy's long-term goal: to ensure that AU Member States demonstrate sustainable biosafety and biosecurity systems aligned with global health security frameworks (e.g., IHR, BWC, UNSCR 1540).

This reconstructed logic model not only defines the intended pathway to impact but has served as the analytical backbone of this evaluation. It has directly informed the evaluation matrix, the development of data collection tools, and the structuring of findings. Results are interpreted at each level of the logic chain to assess whether and how intended changes were achieved.



Stakeholder Mapping and Engagement Strategy

The BSBS Strategy involved a wide range of actors across the Africa CDC Secretariat, RCCs, NPHIs, NRL, relevant government ministries, international organisations as well as development partners and donors who played a significant role in technical and financial support. In addition, development partners and RBB-TWGs play a key role in policy support, technical assistance, and standard setting. The stakeholders in the BBI are across various sectors, including government, human, animal and environmental health, research, academia, national security, agriculture, industry, and civil society. The involvement of each group was crucial for the success of the initiative. Collaboration, information sharing, and effective management of these stakeholders helped to ensure the initiative's effectiveness and long-term sustainability. Effective engagement of these stakeholders is critical in addressing the complex and evolving BSBS challenges that may arise. The evaluation recognized the general population and affected communities as indirect (or end) beneficiaries of the BSBS Strategy. While they are not engaged in implementation or direct recipients of program outputs, they benefit from strengthened national and regional BSBS systems, which contribute to improved health security and outbreak prevention.

A preliminary stakeholder mapping to inform sampling, engagement methods, and the distribution of qualitative and survey tools was done. This preliminary mapping identified key stakeholder categories by their role, level of influence, and expected engagement in the evaluation. This indicative mapping was based on desk review, existing strategic frameworks, and early consultations with Africa CDC and ASLM focal points.

The objective of this preliminary analysis was to inform the design of the evaluation's sampling and engagement strategies, ensuring representation across key implementing partners and institutional levels. This preliminary stakeholder list was validated, expanded and finalized through structured consultations with Africa CDC and RCCs, as well as a targeted review of BSBS implementation records and technical group membership as data collection preparations proceeded. This process ensured the inclusion of relevant, informed, and regionally representative voices across all data collection tools. A summary of the stakeholder categories, their implementation roles, and proposed engagement methods is presented in the Table 1.

Table 1: Stakeholder Mapping for the BSBS Strategic Plan Evaluation

Stakeholder Group	Role in BSBS Implementation	Level	Planned Engagement
International Bodies; WHO, WOAH, FAO, UNEP, GHSI partners such as NTI	Technical guidance and standards, policy and legal advisory, funding	International	KIIs, FGDs
Continental Bodies; Africa CDC HQ, ASLM	Strategic oversight, coordination	Continental	KIIs, cross-regional FGD

Regional Coordinating Centres (RCCs)	Regional implementation and support	Regional	KIIs, IDIs
National Public Health Institutes (NPHIs) & National Reference Labs (NRL)	Technical implementation	National	IDIs, Surveys
Ministries (Health, Agriculture, Environment, security)	National policy and regulatory role	National	KIIs, IDIs
TWG Members	Technical and advisory input	Regional/National	FGDs, Surveys
Trained technical personnel from BSBS programs	Capacity application and practices	National	Surveys, FGDs
Local Communities and indirect Beneficiaries	local monitoring and awareness campaigns	National/sub-national	Not directly interviewed; indirectly captured through implementing stakeholder responses (e.g., NPHIs, labs) and survey analysis
Development Partners and donors (e.g., Global Affairs Canada, World Bank, The Coalition for Epidemic Preparedness Innovations)	Strategic and financial support	External	KIIs

Evaluation Criteria and Questions

5.1 Evaluation Criteria

This end-term evaluation of the BSBS 5-Year Strategy (2021–2025) was guided by internationally recognized evaluation standards, particularly the Organisation for Economic Co-operation and Development-Development Assistance Committee (OECD-DAC) criteria. The evaluation applied a tailored combination of three core DAC criteria namely; effectiveness, impact, and sustainability which were most relevant to the strategic objectives and maturity of the BSBS program at this stage. These criteria were selected in consultation with Africa CDC.

In addition to the DAC criteria, the evaluation also incorporated cross-cutting thematic issues that are critical for learning and forward planning. These included:

- Implementation performance and bottlenecks
- · Challenges encountered during execution
- Lessons learned from the strategy roll-out
- · Overall achievement of the Strategic Plan's intended results
- Strategic recommendations for the 2026–2030 planning cycle

Each evaluation question (EQ) was aligned to at least one DAC criterion and one or more of these thematic issues. This blended approach ensured that the evaluation not only assessed performance and results, but also generated insights to inform institutional learning and strategic decision-making.

5.2 Evaluation Questions

The evaluation was structured around ten overarching Evaluation Questions (EQs), which were developed in close alignment with the objectives and scope outlined in the scope of the evaluation. These questions reflected the key areas of inquiry necessary to assess the performance, outcomes, and strategic relevance of the BSBS 5-Year Strategic Plan (2021-2025).

The EQs were grouped thematically to provide a logical flow of analysis across five broad clusters:

- Overall Strategic Achievement
- Implementation and Effectiveness of Key Interventions
- Impact and System-Level Change
- Sustainability
- Challenges, Lessons Learned, and Recommendations

The questions were intentionally framed to go beyond generic references to outputs, outcomes, and expected results. Instead, they explicitly addressed institutional capacity, cross-country coordination, application of technical training, operational bottlenecks, sustainability prospects, and the future orientation of the strategy. Each EQ was linked to one or more OECD-DAC evaluation criteria (effectiveness, impact, sustainability) and at least one thematic issue relevant to strategic learning and planning.

The full set of evaluation questions is presented below, followed by a matrix summarizing their relationship with the evaluation criteria, thematic issues, judgment criteria, and indicators.

5.2.1 Full set of Evaluation Questions

Cluster 1:

Overall Strategic Achievement

EQ1. To what extent has the BSBS Strategy improved the technical and institutional capacity of Africa CDC, RCCs, NPHIs, and national reference laboratories to prevent, detect, and manage biosafety and biosecurity risks?

Criteria: Effectiveness, Overall Achievement

EQ2. To what extent has the BSBS Strategy strengthened the capacity of Africa CDC, RCCs, NPHIs, and national reference laboratories to coordinate and implement biosafety and biosecurity programs?

Criteria: Effectiveness, Implementation

Cluster 2:

Implementation and Effectiveness of Key Interventions

EQ3. How effective was the regional training and certification program in improving the technical competencies of Biosafety and Biosecurity personnel, and to what extent have trained individuals applied their skills within their institutions?

Criteria: Effectiveness

EQ4. To what extent has the establishment and functioning of the Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) contributed to improved cross-country coordination, knowledge sharing, and strategic alignment?

Criteria: Impact, Effectiveness

EQ5. To what extent have Member States initiated or developed national roadmaps to domesticate the AU BSBS Legal Framework, and what factors influenced their uptake?

Criteria: Effectiveness, Sustainability

Cluster 3:

Impact and System-Level Change

EQ 6. What evidence exists that institutions handling high-risk pathogens have improved their Biosafety and Biosecurity practices as a result of capacity-building, assessments, and regional standards promoted under the strategy?

Criteria: Impact

EQ 7. To what extent has the BSBS Strategy contributed to strengthening sustainable BSBS systems across Member States, including alignment with international frameworks (e.g., IHR, BWC, UNSCR 1540)?

Criteria: Impact

Cluster 4:

Sustainability

EQ 8. Are the investments in training, legal framework development, and regional assessments likely to be institutionalized within Member States or dependent on continued external support?

Criteria: Sustainability, Implementation

Cluster 5:

Challenges, Lessons Learned, and Strategic Recommendations

EQ 9. What were the main operational, institutional, or external challenges that affected the implementation of the BSBS Strategy, and how were they addressed across different levels of the system (e.g., Africa CDC, RCCs, Member States, partners)?

Criteria: Challenges, Implementation

EQ 10. What key lessons from the implementation of the 2021–2025 Strategic Plan should shape the design, Theory of Change, and priorities of the next BSBS Strategic Plan (2026–2030)?

Criteria: Lessons Learned, Recommendations, Strategic Planning

5.2.2 Relationship Between DAC Evaluation Criteria, key evaluation Issues, and Evaluation Questions

The Table 2 presents the relationship between the OECD-DAC evaluation criteria; effectiveness, impact and sustainability, key evaluation issues highlighted in the Evaluation scope, and the EQs guiding this end-term evaluation of the BSBS Strategy (2021–2025). Each EQ was designed to align with at least one DAC criterion and one or more key evaluation issues identified in the Evaluation scope, including: overall strategic achievement, challenges encountered, lessons learned, and recommendations for the next strategy.

The table uses a graduated checkbox system to visually represent the strength of alignment between each EQ and the relevant criteria or issue. This mapping ensures that the evaluation framework provides balanced and comprehensive coverage of both the standard criteria and context-specific priorities, while also identifying which evaluation questions are most critical for exploring particular dimensions of the Strategic Plan's performance, learning, and future direction.

Table 2: Relationship between the DAC Evaluation Criteria, key evaluation issues and the Evaluation questions

Criteria / Issue 50 80 50 80 60 80											
Impact	Criteria / Issue	EQ1	EQ2	EQ3	EQ4	EQ5	EQ6	EQ7	EQ8	EQ9	EQ10
Sustainability	Effectiveness	▽	V	V	▽	▽	~	-	-	-	-
Implementation	Impact	-	-	-	V	~	$\overline{\mathbf{V}}$	V	-	-	-
Overall Achievement Image: Challenges of the control of the contr	Sustainability	-	-	-	-	▽	~	▽	$\overline{\mathbf{V}}$	-	-
Challenges	Implementation	-	▽	~	-	▽	-	-	▽	$\overline{\mathbf{V}}$	~
Lessons Learned Recommendations / Strategic Planning	Overall Achievement		~	-	-	-	-	-	-	-	-
Recommendations / Strategic Planning	Challenges	-	-	-	-	-	-	-	-	V	-
- - - - - - - - - -	Lessons Learned	-	-	-	-	-	-	-	-	▽	✓✓
	Recommendations / Strategic Planning	-	-	-	-	-	-	-	-	-	$\overline{\mathbf{V}}$

Strength of Coverage



5.2.3 Evaluation Matrix for the BSBS 5-Year strategy

The Evaluation Matrix provided the analytical backbone of the end-term evaluation of the BSBS 5-Year Strategy (2021–2025). It served as the principal tool for translating the evaluation objectives and questions into actionable lines of inquiry, ensuring that data collection, analysis, and interpretation remain focused, systematic, and aligned with both the scope of the evaluation and international evaluation standards.

The matrix is structured around ten EQs, clustered thematically and developed in line with the OECD-DAC evaluation criteria namely, effectiveness, impact, and sustainability as well as cross-cutting

evaluation issues such as implementation, challenges, lessons learned, and strategic recommendations. Each EQ was accompanied by clearly defined judgment criteria, specific sub-questions, and a tailored set of indicators to assess performance and change over the strategy period.

A total of 69 indicators were used across the ten EQs:

42

9

15

Forty-two indicators (61%) were sourced directly from the reconstructed intervention logic of the BSBS Strategy. These reflect agreed outputs and outcomes, forming the foundation for assessing institutional and technical performance.

Nine indicators (13%) were adapted from original indicators to better capture learning, application, and systems-level impact-particularly where original indicators were more descriptive than evaluative.

Fifteen indicators (26%) were newly developed to fill essential gaps not addressed in the original logic, especially those related to sustainability, external support dependency, and stakeholder input to inform the next strategy cycle (2026-2030).

Each indicator was linked to specific data sources, disaggregated by primary sources (e.g. Key Informant Interviews) and secondary sources (e.g. program reports, institutional assessments, performance data), supporting a triangulated and diverse evidence base. The matrix ensured alignment between EQs, indicators, and data collection methods, enhancing coherence and clarity across all stages of the evaluation.

This integrated approach balanced accountability to the original strategy with forward-looking learning, ensuring that findings not only assessed past performance but also informed the theory of change and strategic priorities for the upcoming (2026-2030) planning cycle. The summary Evaluation Matrix for the End-Term Evaluation of the BSBS (2021-2025) Strategy is shown in Table 3 and the detailed version in Annex 2

Table 3: Summary Evaluation Matrix for the End-Term Evaluation of the BSBS Strategy

EQ1 - Overall Strategic Achievement

Q1. To what extent has the BSBS Strategic Plan improved the technical and institutional capacity of Africa CDC, RCCs, NPHIs, and national reference laboratories to prevent, detect, and manage biosafety and biosecurity risks?

Evaluation Criteria covered: Effectiveness, Overall Achievement

Specific Evaluation
Questions

- Did the BSBS Strategy support foundational planning and capacity development at NPHIs and NRLs?
- Did infrastructure improvements enable compliance at NPHIs and NRLs?
- Were NPHIs and NRLs adequately assessed and equipped for BSBS implementation?

Judgement criteria		#Indicators
JC.1.1	Strategic planning and capacity readiness of NPHIs and NRLs	2
JC.1.2	Infrastructure upgrades and compliance at NPHIs and NRLs	2
JC.1.3	Equipping and preparedness of NPHIs and NRLs	2

EQ2 - Coordination and Implementation

Q2. To what extent has the BSBS Strategic Plan strengthened the capacity of Africa CDC, RCCs, NPHIs, and national reference laboratories to coordinate and implement biosafety and biosecurity programs?

Evaluation Criteria covered: Effectiveness, Implementation					
Specific Evaluation Questions	• Was the staffing at Africa CDC and RCCs sufficient to support BSBS coordination and implementation?				
	• Did Member States receive timely and high-quality support from Africa CDC and RCCs?				
	Did RBB-TWGs actively contribute to and support BSBS implementation?				
Judgement criteria		#Indicators			
JC.2.1	Biosafety and Biosecurity staffing at Africa CDC and RCCs	2			
JC.2.2	Timeliness and quality of technical support to Member States	2			
JC.2.3	Use and engagement of RBB-TWGs in BSBS implementation 2				
FO3 - Training and Competency Building					

EQ3 - Training and Competency Building

Q3. How effective was the regional training and certification program in improving the technical competencies of biosafety and biosecurity personnel, and to what extent have trained individuals applied their skills within their institutions?

Evaluation Criteria covered: Effectiveness					
Specific Evaluation Questions	Was the regional training and certification program for BSBS effectively established and implemented?				
	• Did training participants improve in knowledge and apply skills at institutional level?				
	Were RCoEs successfully established and used as regional training hubs?				
Judgement criteria		#Indicators			
JC.3.1	Design and delivery of regional BSBS training programs	3			
JC.3.2	Training effectiveness and knowledge application	2			
JC.3.3	Establishment and functionality of RCoEs	2			

EQ4 - Cross-country Collaboration and Alignment

Q4: To what extent has the establishment and functioning of Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) contributed to improved cross-country coordination, knowledge sharing, and strategic alignment?

Evaluation Criteria covered: Impact, Effectiveness			
Specific Evaluation	Were RBB-TWGs established and positioned to support regional coordination?		
Questions	Have RBB-TWGs met regularly and functioned as intended?		
	• Did RBB-TWGs contribute meaningfully to the success of regional BSB.	S interventions?	
Judgement criteria		#Indicators	
JC.4.1	Establishment and structure of RBB-TWGs	2	
JC.4.2	Meeting frequency and operational functionality of TWGs	3	
JC.4.3	Contribution of TWGs to BSBS implementation	1	
FOS - Legal Framework Domestication			

EQ5 - Legal Framework Domestication

Q5. To what extent have Member States initiated or developed national roadmaps to domesticate the AU BSBS Legal Framework, and what factors influenced their uptake?

Evaluation Criteria: Effectiveness, Sustainability			
Specific Evaluation Questions	Was a legal framework and supporting advocacy strategy developed to enable Member State domestication?		
	• Were advocacy efforts and technical assistance provided to enable Member States to domesticate the BSBS legal framework?		
	• To what extent have Member States progressed in planning and complet domestication of the BSBS framework?		
Judgement criteria		#Indicators	
JC.5.1	Development of enabling strategy for legal framework rollout	2	
JC.5.2	Engagement and support to Member States for domestication	2	
JC.5.3	Progress in legal domestication by Member States	2	
	, , , , , , , , , , , , , , , , , , ,		

EQ6 - Risk Management and Compliance

Q6. What evidence exists that institutions handling high-risk pathogens have improved their biosafety and biosecurity practices as a result of capacity-building, assessments, and regional standards promoted under the strategy?

Evaluation Criteria covered: Impact

Evaluation Criteria covered. Impact		
Specific Evaluation Questions	 Were the tools and framework for institutional certification developed and made available for use? 	
	Were assessors and trainers adequately prepared to support certific risk institutions?	cation of high-
	 Have institutions been assessed, certified, and improved in compliance and biosecurity standards? 	with biosafety
Judgement criteria		#Indicators
JC.6.1	Development of certification tools and regulatory framework	2
JC.6.2	Training and availability of assessors and trainers	4
JC.6.3	Institutional assessment, certification, and performance	3

EQ7 - System Strengthening and Global Alignment

Q7. To what extent has the BSBS Strategic Plan contributed to strengthening sustainable biosafety and biosecurity systems across Member States, including alignment with international frameworks (e.g., IHR, BWC, UNSCR 1540)?

Evaluation Criteria covered: Impact

Specific Evaluation
Questions

- Are BSBS elements integrated into national systems?
- Are international obligations met?
- Is there evidence of sustainability?

Judgement criteria		#Indicators
JC.7.1	International alignment	2
JC.7.2	Institutional ownership	2
JC.7.3	Sustainability readiness	2

EQ8 - Sustainability of Investments

Q8: Are the investments in training, legal framework development, and regional assessments likely to be institutionalized within Member States or dependent on continued external support?

Evaluation Criteria covered: Sustainability, Implementation

Specific Evaluation
Questions

- Are systems ready to sustain gains?
- Are institutional structures in place?
- What risks exist for backsliding?

Judgement criteria		#Indicators
JC.8.1	National ownership	2
JC.8.2	Institutionalization of tools	2
JC.8.3	Dependency on external support	2

EQ9 - Implementation Challenges and Mitigation

Q9: What were the main operational, institutional, or external challenges that affected the implementation of the BSBS Strategic Plan, and how were they addressed across different levels of the system (e.g., Africa CDC, RCCs, Member States, partners)?

Evaluation Criteria covered: Challenges, Implementation

Specific Evaluation	What were the most common implementation challenges?
Questions	• Were they addressed effectively?

• What were the lessons?

Judgement criteria		#Indicators
JC.9.1	Operational delays	2
JC.9.2	Systemic and institutional constraints	2
JC.9.3	Mitigation responses	2

EQ10 - Strategic Learning and Recommendations

Q10: What key lessons from the implementation of the 2021–2025 Strategic Plan should shape the design, theory of change, and priorities of the next BSBS Strategy (2025–2030)?

Specific Evaluation Questions	What worked well?What failed or underperformed?What priorities should drive the next strategy?	
Judgement criteria		#Indicators
JC.10.1	Reflections on successful practices	2
JC.10.2	Identified gaps and misalignments	2
JC.10.3	Recommendations for future planning	2

Evaluation approach andMethodology

6.1 Evaluation Approach

The evaluation of the Africa CDC BBI 5-Year Strategy (2021-2025) was conducted using a consultative, participatory, multi-faceted and evidence-based approach to ensure a comprehensive assessment of the initiative's achievements, challenges, and lessons learned. The overall objective was to assess the effectiveness, implementation, and impact of the strategy to inform the development of the next strategy (2026-2030). The approach integrated quantitative and qualitative methodologies to capture diverse perspectives from key stakeholders, including government institutions, regional bodies, implementing partners, and technical experts. The evaluation will be guided by the Theory of Change framework, including assessing how inputs and interventions have translated into measurable outcomes in BSBS across AU Member States.

6.1.2 Key principles of the Approach

Stakeholder-Centric Evaluation

In order to satisfactorily deliver this assignment, key stakeholders were closely involved to ensure that it is a consultative process.

- Engaging Africa CDC, ASLM, AU Member States, regional technical working groups, and implementing partners through consultations.
- Ensuring active participation through interviews, focus groups, and validation workshops.

Mixed-Methods Approach

- Incorporating quantitative indicators from the Monitoring & Evaluation (M&E) framework to assess program impact.
- Combination of desk reviews, surveys, key informant interviews, and focus group discussions to triangulate data sources.

Outcome-Oriented Evaluation

- Measuring progress based on impact, outcome, and output-level indicators in the M&E Framework.
- Evaluating capacity-building efforts, regulatory advancements, and certification frameworks.

Lessons Learned & Forward-Looking Recommendations

- Identifying best practices and gaps in strategy implementation.
- Providing actionable recommendations to strengthen biosafety and biosecurity governance in Africa.

6.2 Evaluation Methodology

The methodology for this end-term evaluation of the BSBS 5-Year Strategic Plan (2021-2025) was designed to respond to the objectives and expectations outlined in the scope of evaluation while ensuring methodological rigor, stakeholder inclusiveness, and contextual relevance. It built on a theory-informed and utilization-focused approach, aligned with key OECD-DAC evaluation criteria-namely, effectiveness, impact, and sustainability and integrated cross-cutting issues such as implementation challenges, lessons learned, and strategic recommendations.

The evaluation adopted a mixed-methods design, combining qualitative and quantitative data collection techniques. This approach ensured comprehensive coverage of institutional, regional, and national experiences, while enabling triangulation across different sources of evidence. The methodology was structured around the EQs and matrix developed during the inception phase and was tailored to accommodate the complexity of BSBS implementation across multiple levels and actors. This section outlines the key elements of the evaluation methodology, including data collection methods, data sources, sampling strategy, data analysis plans, ethical considerations, and limitations.

The full detailed methodology is included in Annex 3.

6.2.1 Data collection methods

The evaluation employed multiple complementary data collection methods to capture both the strategic and operational dimensions of the BSBS Strategic Plan. These included desk reviews, key informant interviews (KIIs), in-depth interviews (IDIs), focus group discussions (FGDs), surveys, benchmarking exercises, and SWOT analysis. Data collection methods were selected to capture institutional, regional, and national experiences while ensuring triangulation across different sources.

6.2.1.1 Desk Review

A desk review was conducted to establish the foundation for the evaluation. This involved reviewing strategy documents, progress reports, assessment reports, meeting minutes, training records, and partner publications to understand the strategy's design, implementation context, outputs, and outcomes. Insights from the desk review informed indicator refinement, development of data collection tools, and evaluation matrices.

6.2.1.2 Qualitative methods

Qualitative methods were central to understanding contextual factors, stakeholder perceptions, and operational dynamics that cannot be captured quantitatively.



Key Informant Interviews (KIIs): Targeted strategic-level stakeholders including Africa CDC, RCCs, NPHIs, RBB-TWGs, ministries, and development partners to capture insights on strategy design, coordination, and results.



In-depth Interviews (IDIs): Focused on operational-level implementers, including biosafety officers, laboratory managers, and technical staff, to explore implementation experiences, challenges, and successes.



Focus Group Discussions (FGDs): Engaged groups of field-level stakeholders such as RBB-TWG members, laboratory personnel, and mid-level technical officers to elicit collective perspectives on BSBS activities, coordination, and lessons learned.

Semi-structured interview guides and discussion templates were used (Annexes 4–6). Qualitative insights were triangulated with desk review and survey data to enhance the reliability of findings.

6.2.1.3 Quantitative methods

Quantitative methods were used to generate measurable data on the reach, effectiveness, and perceived outcomes of the BSBS 5-Year Strategy (2021-2025). The primary quantitative tool was an online survey targeting a broad sample of trained personnel, technical working group members, national focal points, and public health professionals. The survey provided standardized data to complement qualitative findings, allowing for trend analysis, regional comparison, and aggregation of stakeholder perspectives across Member States. Surveys were used as a quantitative data collection method to gather standardized information from a broad range of stakeholders across AU Member States. It was administered through distribution of structured online surveys which allowed for wide geographic reach and efficient data management. Survey instruments included closed- and open-ended questions and were translated into French to maximize accessibility across AU Member States, Annex 7. Surveys used Likert-scale questions to measure attitudes or satisfaction, closed and open-ended questions to gather quantitative and qualitative feedback. The outputs included the quantitative data which was be analyzed statistically, and that was complemented by qualitative responses to explore issues in more depth. Surveys captured perceptions on training effectiveness, coordination, institutional capacity, and sustainability.

6.2.1.4 Benchmarking and comparison

The purpose of this component was to compare the outcomes and progress of the BSBS Strategic Plan with other similar BSBS programs and international standards. This was carried out by identifying peer initiatives and frameworks — including those from WHO, the Global Health Security Agenda (GHSA), and national-level biosafety programs — and reviewing their strategic goals, methods of implementation, and achievements.

One specific comparative case used was the ASEAN Regional Strategic and Action Plan for Biosafety and Biosecurity (2019–2023), which shares similar objectives with the BSBS strategy. The benchmarking helped identify areas where the BSBS initiative aligns well with global standards and where further adaptation or scaling may be needed.

6.2.1.5 SWOT Analysis

As part of the overall analysis, a SWOT (Strengths, Weaknesses, Opportunities, Threats) framework was applied to synthesize internal and external factors that influenced the implementation and impact of the BSBS Strategic Plan. The SWOT analysis drew from coded qualitative data, survey responses, and document review to identify patterns of institutional and strategic performance. Strengths and weaknesses reflected internal attributes (e.g., Africa CDC coordination, training quality), while opportunities and threats reflected external factors (e.g., political buy-in, donor dependency). This analysis informed the conclusions and recommendations sections and was used to prioritize areas for strategic focus in the next planning cycle.

Table 4: Main findings of the SWOT analysis conducted as part of this evaluation

Strengths

Strong Africa CDC leadership and convening power Well-received tiered training and certification model Availability of technical tools and assessment checklists Regional TWG structures facilitated coordination

Weaknesses

Technical staffing gaps at Africa CDC
Inconsistent institutional readiness among MS
Limited post-training mentorship and follow-up
Language barriers and delays in material translation
Lack of formal institutionalization in many Member States

Opportunities

Integrate BSBS into national budgets and organograms Leverage existing training platform to reach other sectors Promote career development pathways for BSBS professionals Scale up certification to more labs and institutions

Threats

Current cuts on Official Development Assistance (ODA)
Ongoing donor dependency in many countries
Risk of momentum loss post-strategy period
Political turnover and competing priorities
Low awareness in non-human health sectors

Through the employment of a combination of these methods, a comprehensive evaluation of the BBI, addressing both its strategic impacts and its operational outcomes will be effectively conducted.

6.2.2 Data sources

The evaluation was drawn on both primary and secondary data sources to ensure a comprehensive, credible, and triangulated evidence base. Primary data was collected directly from key stakeholders involved in the design, implementation, and oversight of the BSBS 5-Year Strategic Plan (2021-2025). This included Africa CDC staff, RCCs, NPHIs, NRL, members of RBB-TWGs, public health professionals, and development partners as listed in Annex 8. Primary data was gathered through KIIs, IDIs, FGDs, and an online survey targeting a broad group of trained personnel and national focal points.

Secondary data sources included relevant documentation such as the BSBS Strategic Plan, the M&E framework, annual progress and activity reports, strategic and legal framework documents, training records, meeting minutes, technical guidelines, assessment reports, and related partner publications. These documents provided background context, support indicator verification, and enable comparison of baseline, target, and actual performance data across the strategy period.

6.2.3 Sampling Strategy and Stakeholder Engagement

The evaluation adopted a purposive, multi-level sampling strategy designed to ensure broad and meaningful engagement with stakeholders across all five Africa CDC RCCs and at the continental, regional, and national levels. The sampling was structured to align with the evaluation's mixed-methods design, which includes KIIs, IDIs, FGDs, and an online survey.

Stakeholders were initially categorized into groups based on their roles in the design, implementation, coordination, or oversight of the BSBS Strategic Plan.

These include:

- Africa CDC headquarters staff (strategy leads, technical focal points, M&E, legal)
- Regional Coordinating Centre (RCC) representatives
- National Public Health Institutes (NPHIs), national reference laboratories, and trained technical personnel
- Members of the Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs)
- · Relevant ministries (Health, Agriculture, Environment) involved in national implementation
- Development partners and donors supporting biosafety and biosecurity in Africa

A preliminary stakeholder map informed the sampling approach, but the list of specific individuals and institutions was refined and finalized during the data collection planning phase, in close consultation with Africa CDC and RCC focal points. This staged approach allowed for ensuring that all relevant voices were captured, while maintaining flexibility to accommodate emerging information, regional access, and the evolving institutional landscape.

6.2.3.1 Qualitative Sampling Strategy

A purposive, stakeholder-based sampling approach was applied to qualitative data collection, including Key Informant Interviews (KIIs), In-depth Interviews (IDIs), and Focus Group Discussions (FGDs). The strategy ensured representation of strategic, technical, and field-level actors across all five RCCs, with participants selected for their institutional roles, involvement in the BSBS Strategic Plan, and capacity to provide relevant insights on implementation, coordination, and outcomes.

Sampling emphasized diversity and saturation rather than fixed quotas. Planned numbers were indicative and adjusted based on stakeholder availability, feasibility, and the principle of information saturation—data collection continued until no new themes emerged. Interpretation services were provided where necessary to facilitate inclusivity.



Key Informant Interviews (KIIs): Targeted high-level stakeholders from Africa CDC, RCCs, NPHIs, ministries, and development partners. Larger RCCs with more Member States and institutions were allocated proportionally more KIIs to capture regional variation. While 30 were planned, 42 were conducted.



In-depth Interviews (IDIs): Focused on technical experts and implementers such as biosafety officers, laboratory managers, NPHI focal points, and One Health representatives. The target of 40 was adjusted to 29, based on saturation.



Focus Group Discussions (FGDs): Designed to capture collective perspectives of mid-level technical staff, RBB-TWG members, and laboratory personnel. Ten FGDs were planned, though seven were conducted. It was a great challenge to organise an FGD with the recommended number, of the 7 we had, the composition ranged from (1-6) due to reasons such as internet challenges, competing priorities among others.

This adaptive sampling approach balanced methodological rigor with real-world feasibility, ensuring broad stakeholder representation while prioritizing data quality and triangulation.

6.2.3.2 Quantitative Sampling Strategy

The quantitative component of the evaluation was conducted through an online survey using Kobocollect targeting a broad cross-section of stakeholders involved in the implementation of the BSBS Strategic Plan across the Africa CDC Secretariat, RCCs, NPHIs, NRLs, and relevant animal and plant health sectors. Respondents included individuals in technical, programmatic, and policy-related roles who have directly or indirectly contributed to or interacted with BSBS activities during the implementation period. A French translated version of the survey form was provided.

A non-probability purposive sampling approach was employed, aiming to reach as many relevant stakeholders as possible across the five regions. Survey distribution targeted technical staff, trained personnel, national focal points, and other stakeholders. A minimum of 300 responses was sought for meaningful disaggregation by region and institution. Dual participation in interviews and surveys was allowed to support triangulation, with overlap managed to maintain data integrity.

Table 5 shows the relevant stakeholder groups.

Table 5: Key Stakeholder Groups Relevant to the Evaluation of the BSBS Strategic Plan

Stakeholder Group	No. of countries	Planned KIIs	Adjusted KIIs	Actual KIIs	Planned IDIs	Adjusted IDIs	Actual IDIs	Planned FGDs	Actual FGDs	Surveys (Estimates)	Actual Nos.
Western RCC	15	7	8	8	9	8	10	3	2	65	34
Eastern RCC	14	6	7	7	9	8	9	3	1	59	25
Southern RCC	10	5	5	5	6	5	3	2	2	54	30
Central RCC	9	3	5	5	6	5	3	1	1	49	30
Northern RCC	7	3	3	3	4	4	4	1	1	43	42
Africa CDC secretariat,	N/A	6	12	14	6	0	0	0	0	30	0
ASLM & partners											
Total	55	30	40	42	40	30	29	10	7	300	199

6.2.4 Data Analysis Plan

The evaluation applied a mixed-methods approach, integrating both qualitative and quantitative data to assess the relevance, effectiveness, coordination, and outcomes of the Biosafety and Biosecurity Strategic Plan (BSBS). Analysis was structured around the evaluation questions, judgment criteria, and indicators outlined in the evaluation matrix, including those drawn from the reconstructed intervention logic.

6.2.4.1 Quantitative Data Analysis

Quantitative data analysis was carried out on two main fronts:

Survey Data Analysis



Survey data was cleaned and analysed using statistical software such as Excel, Epi Info, SPSS or STATA. Descriptive statistics including frequencies, means, medians and percentages were used to summarize stakeholder perspectives on the effectiveness, implementation, impact, lessons learned and challenges of the BSBS Strategic Plan.

Responses were disaggregated by region (RCC), sector, and institutional level (national, regional, continental, institutional). Cross-tabulations may be conducted to explore relationships between stakeholder attributes and their perceptions.

Indicator-Based Analysis (from Intervention Logic)



Quantitative data linked to the indicators defined in the reconstructed intervention logic were specifically analysed to assess achievement against targets. Where baseline and target values existed (for both output and outcome indicators), actual progress was measured and expressed as a percentage of achievement.

Indicator results were analysed against the planned results chain to assess both direct outputs and intermediate outcomes, and were synthesized in tables and dashboards to show variations across regions or institutional types.

6.2.4.2 Qualitative Data Analysis

Qualitative data from Key Informant Interviews (KIIs), In-depth Interviews (IDIs), and Focus Group Discussions (FGDs) were transcribed and imported into ATLAS.ti for structured thematic analysis. A codebook was developed based on the evaluation matrix, with codes aligned to each evaluation question and associated judgment criteria. Additional inductive codes were added to capture emerging themes and unanticipated insights from participants. Coding was conducted iteratively, and key quotations were extracted for synthesis. Each Priority Area was analyzed separately, allowing for comparative insights across regions, institutional levels, and stakeholder types. Final thematic outputs were mapped back to the intervention logic to assess linkages between inputs, activities, outputs, and outcomes. Verbatim quotes were selected to illustrate core findings and variation in perspectives. This approach supported triangulation with survey and document review data, and ensured a rigorous and grounded analysis of implementation and results.

ATLAS.ti software was used to generate themes and sub-themes on the data. Data was coded, a codebook developed in ATLAS.ti and extracted into Microsoft word text, and responses were categorized into themes and subthemes. Thereafter interpretations were made. Thematic coding enabled comparison across regions (RCCs), stakeholder types, and technical domains. Representative quotes were extracted to illustrate findings, explain variations, and validate quantitative trends. The evaluation focused on capturing results across six Priority Areas (PAs) of the BSBS Strategy and used a reconstructed intervention logic and final evaluation matrix as analytical anchors.

✓ Priority Area Group Mapping

Code Group Name	EQs to Add	Code Prefixes
PA1_StrategicFocus_AfricaCDC	EQ1, EQ2, EQ10	EQ1_, EQ2_, EQ10_
PA2_TWG_RegionalCoordination	EQ2, EQ4	EQ2_, EQ4_
PA3_Legal_Framework	EQ5	EQ5_
PA4_HCAT_Certification	EQ6	EQ6_
PA5_Training_Certification	EQ3	EQ3_
PA6_Strengthening_MS_Capacity	EQ1, EQ6, EQ7, EQ8	EQ1_, EQ6_, EQ7_, EQ8_

6.2.4.3 Triangulation and Integration

Qualitative and quantitative findings were triangulated to validate results and build a comprehensive picture of the program's performance. For each evaluation question, data from interviews, FGDs, surveys, and the indicator tracking analysis was synthesized. This helped contextualize numeric trends, explain variations, and enhance the credibility of conclusions.

6.2.4.4 Findings, Interpretation and Reporting

The presentation of findings was described by the Six BSBS Priority Areas structured around the evaluation questions and aligned with the judgment criteria and indicators outlined in the evaluation matrix. Quantitative results were presented using descriptive statistics, summary tables, and graphs, while qualitative data was synthesized thematically and supported with illustrative quotes. Findings were interpreted in relation to the Strategic Plan's Theory of Change and the reconstructed intervention logic. Particular attention was paid to variations across RCCs, stakeholder groups, and technical domains. The analysis also considered contextual factors and assumptions that may have influenced implementation or results.

Triangulation of quantitative and qualitative data supported robust interpretation and ensured that conclusions were evidence-based. Data visualisation including summary tables, charts, and quotes were created to support key findings. Recommendations were directly informed by the findings and clearly linked to observed trends, gaps, and opportunities for future strategic planning.

Report Structure and Organization

The evaluation report is structured around the six Priority Areas of the Africa CDC BSBS Strategy (2021–2025). This thematic organization was chosen to ensure direct alignment with the Strategic Plan itself, as well as with the evaluation questions and the reconstructed intervention logic. Each Priority Area is analyzed in terms of its effectiveness, implementation progress, early signs of impact, and sustainability, drawing on both quantitative and qualitative data sources. While the report does not follow a strict input–output–outcome–impact format, it provides a comprehensive results-oriented synthesis that addresses the full results chain in a format more suitable for strategic-level evaluation. This approach enables clearer insight into what worked, what challenges emerged, and what can be strengthened in the next strategy phase.

6.2.5 Ethical Considerations

The evaluation adhered to standard ethical principles, ensuring that all participants were treated with respect, dignity, and confidentiality. Informed consent was obtained from all respondents, who were clearly informed about the purpose of the evaluation, their rights, and the voluntary nature of participation. Participants were allowed to decline to answer questions or withdraw at any time without consequence.

All data was used solely for the purpose of this evaluation. Data was anonymized during analysis and reporting, and all information was stored securely to protect participant privacy. The principle of "do no harm" was applied, taking care to avoid any form of psychological, professional, or reputational harm. The evaluation was conducted with full respect for the dignity, rights, and cultural context of all stakeholders involved especially during interviews and group discussions.

6.2.6 Limitations and Mitigation Strategies

While every effort was made to ensure a comprehensive, inclusive, and high-quality evaluation process, several potential limitations were anticipated. These are outlined Table 6 below, along with corresponding strategies to mitigate their impact. This approach ensured that potential challenges were acknowledged and addressed, supporting the credibility, inclusiveness, and usability of the evaluation findings.

Table 6: Anticipated Limitations and Corresponding Mitigation Strategies for the Evaluation

Potential Limitation	Mitigation Strategy
Non-response or Low Survey Participation	Disseminate the survey through trusted institutional channels and RCC focal points Send timely reminders to encourage participation Ensure the survey is brief, user-friendly, and accessible across devices Clearly communicate the purpose and importance of the evaluation
Limited Availability of Key Informants	Disseminate the survey through trusted institutional channels and RCC focal points Send timely reminders to encourage participation Ensure the survey is brief, user-friendly, and accessible across devices Clearly communicate the purpose and importance of the evaluation Schedule interviews well in advance with flexible timing options Offer alternatives such as written responses or shorter interviews Identify and engage equally knowledgeable alternate respondents where necessary
Uneven Regional Representation	Collaborate closely with RCC focal points to encourage balanced outreach Monitor participation levels in real-time and increase follow-up in underrepresented regions Ensure language and contextual relevance of tools to improve accessibility
Limited Access to Secondary Data and Documentation	Request key documents early through formal channels. use qualitative insights to supplement gaps Cross-check with key informants and partners to fill documentation gaps
Potential Bias in Self- Reported Data	Ensure anonymity in survey responses to encourage honesty Triangulate self-reported data with multiple sources (e.g., program records, multiple perspectives) Use neutral, non-leading language in tools and probes
Language or Terminology Barriers	Pre-test tools to ensure clarity Use standardized definitions where possible Provide explanations during interviews or survey



Work Plan andManagement

The evaluation was implemented from 3rd April 2025 - 30 June 2025 following a structured work plan that includes inception, data collection, analysis, and reporting phases. The work plan ensured that all activities were aligned with the objectives of the evaluation and that deliverables were completed within the agreed timeframe.

7.1 Work Plan

The evaluation was implemented in five major phases: project inception, data collection, draft report writing, report validation and final reporting. Each phase followed a structured timeline to ensure timely delivery of key milestones as shown in Annex 9.

7.2 Quality Assurance

The evaluation applied rigorous quality assurance measures throughout all stages of implementation. This included the development and pretesting of tools, standardized data collection protocols, and thorough data cleaning procedures. Triangulation of multiple data sources enhanced the validity of findings, while internal review processes ensured accuracy, coherence, and alignment with the evaluation framework. Ethical standards, including confidentiality and secure data handling, were strictly upheld to safeguard the integrity of the evaluation and its results.

Africa CDC played a central role in quality assurance by reviewing data collection tools, providing oversight during implementation, participating in validation processes, and reviewing draft deliverables. Their engagement helped ensure that the evaluation remained relevant, technically sound, and aligned with institutional priorities.

7.3 Risk management and mitigation measures

The evaluation anticipated several potential risks, including low survey response rates, limited availability of key informants, uneven regional participation, and delays in accessing documents. To mitigate these risks, the evaluation team implemented targeted measures such as early engagement with RCC focal points, flexible scheduling of interviews, timely follow-ups, and ongoing coordination with Africa CDC. These strategies will help ensure that data collection remains inclusive, timelines are maintained, and the evaluation is successfully completed within scope and schedule, as shown in Table 7.

Table 7: Anticipated Limitations and Corresponding Mitigation Strategies for the Evaluation

Potential Limitation	Mitigation Strategy
Low survey response rates	Engage RCC focal points and partners early, send reminders, ensure the survey is brief and relevant
Limited availability of key informants	Schedule interviews flexibly, offer written response options, and identify alternates in consultation with Africa CDC
Uneven regional participation	Track participation in real time and increase outreach in underrepresented RCCs
Delays in accessing secondary data or documentation	Request documents early and use qualitative or survey data to fill information gaps
Data quality or inconsistency issues	Conduct internal checks, standardize tools and training, and review data before analysis
Timeline disruptions or delays	Maintain regular coordination with Africa CDC and allow limited flexibility in the schedule

7.4 Outreach and Dissemination of Findings

An effective outreach and dissemination plan is essential to ensure that the evaluation findings are not only communicated, but also understood, owned, and used by key stakeholders. The goal is to promote learning, accountability, and informed decision-making across Africa CDC, RCCs, and partner institutions. The evaluation will adopt a multi-channel dissemination approach, aligned with the needs and preferences of different audiences. The primary output will be the final evaluation report, which will include an executive summary, visual data highlights, and actionable recommendations.

8 Results

8.1 DEMOGRAPHICS OF RESPONDENTS

Overall, for the end-term evaluation of the Africa CDC Biosafety and Biosecurity Strategic Plan evaluation, 53/55 (96%) of African Union Member States were represented in both quantitative and qualitative methods. Even then there were efforts to reach out to the two missing Member States though it was unsuccessful.

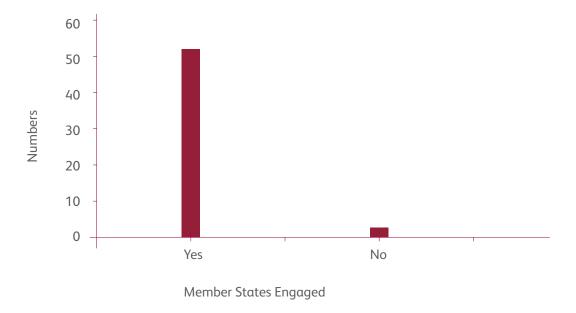


Figure 2: Member States that participated in the Evaluation

Two hundred and ninety-seven respondents participated in the evaluation. Of these, 199 (67%) participated in the survey while 98 (33%) participated in the qualitative data collection. Of the primary institutions of the evaluation participants, 64% were from ministry or government agencies, National Reference Laboratories, Regulatory Authority and National Public Health Institutes and 21% were from Academic and Research Institutions as shown in Table 8 below.

Table 8: Primary institutions of the Evaluation participants

Primary institution (n=290)	Frequency (Qualitative)	Frequency (survey)	Total	Percentage (100%)
Ministry or Government Agency (e.g. Ministry of Health, Agriculture, Environment, Defence, etc.), National Public Health Institutions, National	49	137	186	64.1
Reference Laboratories, Regulatory Authority				
Academic or Research Institution	24	38	62	21.4
Development or Implementing Partner	5	6	11	3.9
Continental Bodies (Africa CDC, ASLM)	6	1	7	2.4
Private Sector / Industry (e.g., diagnostics, biotechnology, pharmaceutical, private labs)	5	4	9	3.1
International Bodies	3	2	5	1.7
Others (Civil Society, NGO, etc)	6	4	10	3.4

Of the 193 participants 38 (19.7%) were from West Africa RCC, 44 (22.8%) Southern, 34 (17.6%) Eastern, 46 (23.8%) Northern and 31 (16.1%) Central Africa RCC.

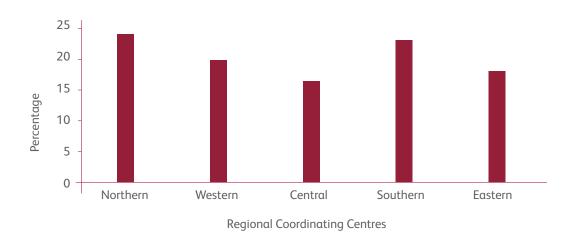


Figure 3: Survey respondents by Regional Coordinating Centres

For the 98 participants in the qualitative methods, 18 (18.4%) were from the Southern RCC, 12 (12.2%) Central, 22 (22.4%) Eastern, 11 (11.2%) Northern and 21 (21.4%) Western, and 14 (14.4%) others (Africa CDC and partners).

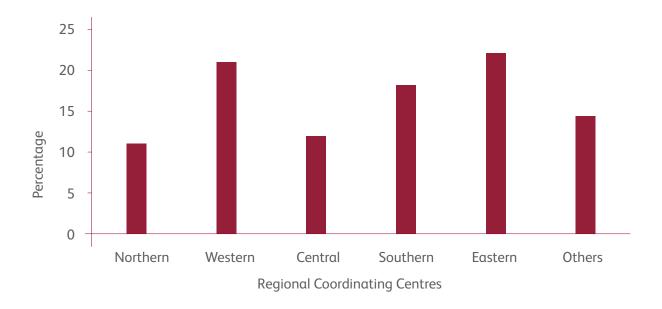


Figure 4: Qualitative study participants by Regional Coordinating Centres

Table 9: Evaluation participants by Regional Coordinating Centres

RCC	Participants in Sur	vey	Participants in Qualitative Data Collection		
	Number %		Number	%	
Northern	46	23.8	11	11.2	
Western	38	19.7	21	21.4	
Central	31	16.1	12	12.2	
Southern	44	22.8	18	18.4	
Eastern	34	17.6	22	22.4	

8.2 MAIN ACHIEVEMENTS FROM THE STRATEGIC OBJECTIVES

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.

The BSBS Initiative (BBI) was implemented across six broad categories and the main achievements are discussed under each Priority Area.

8.2.1 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 put pressure on the existing staff within the laboratory division of Africa CDC. At the time there were only two dedicated staff (one senior and one technical staff) for BBI. In the long term, Africa CDC proposed 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 Regional Coordinating Centres (RCCs). The 2 senior staff were to 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 would work closely with African Union MS, partners and regional experts in the implementation of activities at the MS level. This priority area was partially achieved, with two dedicated staff (40%) of the planned number. In order to compensate for the staff limitation at Africa CDC, subject matter experts in Member States were effectively used and TWGs also provided support for the regional coordination of activities.

The Strategic Plan states that 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, four (4) RCCs are functional including Western, Central, Southern and Eastern RCCs all with limited staffing. Northern RCC is operating from Addis Ababa until its establishment in the Northern region.

Effectiveness

Africa CDC's elevation of BSBS as a strategic priority was widely recognized as instrumental in enhancing regional coordination and attracting international collaboration. By integrating BSBS into its core mission, Africa CDC provided visibility and legitimacy that extended beyond the continent. As one international partner noted:

"Africa CDC taking this one as a priority aspect of its mission has been really important not just for the African region, but also for external organizations like CEPI so that we have clear ways of coordinating, collaborating in areas of mutual interest."

This leadership role underscored the strategic effectiveness of the BSBS Plan in positioning BSBS as a continental agenda, catalyzing partnerships and elevating institutional engagement at both regional and global levels.

The Africa CDC BSBS Strategy served as a central reference point for Member States. Stakeholders frequently described it as a hands-on, practical tool—particularly valuable in settings where no prior national frameworks existed:



"Yes, the strategic plan actually it became like a dictionary for us."

The availability of strategic templates, SOPs, and structured technical materials enabled several Member States to begin or accelerate the establishment of their national BSBS efforts:

"Now... we do have documents. We receive supporting tools from Africa CDC that we can use directly."

According to the intervention logic, Africa CDC met its foundational output targets by producing technical guidance and distributing it across all regions between 2021 and 2024. These tools in Table 10 below helped catalyze country-led implementation processes.

Table 10: Africa CDC Technical Guidance Tools

Technical Guidance Tools	
A Biosafety and Biosecurity Legal Framework for the Africa Region	Regional Framework for Institutions Handling High Risk Pathogens
A Regional Training and Certification Program	Guidance Framework for the Establishment of HCATs lists

Stakeholders also credited Africa CDC's strategic leadership with generating high-level political traction for BSBS. As one senior informant explained:

*"It was also helpful in kind of building the political momentum... having Africa CDC really put their weight behind something demonstrates to national leaders that this is a priority area to really pay attention to."

Beyond documentation, Africa CDC's convening power—via regional consultations and planning sessions—contributed to institutional alignment and regional coherence. These efforts were seen by many as a game changer.

However, while the strategic plan was widely appreciated, several respondents pointed to important limitations. In some countries, BSBS integration was not fully institutionalized

 \checkmark "We need to make the institution accept the process and make it part of their routine. We are still pushing the institutions."

In addition, MS indicated that some of the technical guidance materials often required country-level adaptation.

st 'Some of the documents we received needed adaptation... they weren't always usable as-is."

Implementation

Implementation of the BSBS Strategy (2021–2025) was structured as a cascade model of Africa CDC oversight through Regional Coordinating Centres (RCCs), while Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) served as operational platforms to disseminate technical quidance, convene peer learning, and align country-level efforts.

RBB-TWGs showed/demonstrated their oversight roles e.g. they were involved in the review and endorsed:

- Regional BSBS Legal Framework
- Regional Training and Certification Program
- · Regional Framework for Institutions Handling High Risk Pathogens
- Status report on implementation of Biological Weapons Convention in Africa
- Guidance Framework for the Establishment of HCATs lists

During the implementation of the BSBS Strategy (2021–2025), Africa CDC operated with a lean team of two dedicated staff—one senior and one technical focal person—based at headquarters, covering coordination, partner engagement, and technical follow-up across all five RCCs. This represented only 40% of the intended staffing structure, resulting in limited reach and constrained capacity to provide hands-on support to Member States.

Regional technical staffing to support the five RCCs was not fully realized. As one senior stakeholder commented:

 ★"There are few staff to follow up... they do their best, but the scope is too wide for the team
currently in place."

This staffing shortfall had clear implications for Africa CDC's ability to provide timely, structured technical assistance across the continent. Survey data showed that only 34% of respondents (n=147) reported receiving any technical support related to BSBS activities under the strategic plan. Among the 49 respondents who did receive support, only 30.6% said the support met their needs "to a great extent" — highlighting the limits of centralized coordination capacity.

While Africa CDC achieved key foundational outputs (e.g., development of strategic documents, guidance templates, and convening of RBB-TWGs), the limited staffing structure constrained broader institutional support functions and follow-up at Member State level. One respondent noted:

*"Some requests were not responded to on time... sometimes we just didn't get the technical support when we needed it."

Furthermore, the implementation capacity of RCCs remained variable. Of the five RCCs, only three (Central, Eastern, and Southern) were considered operational by the end of the strategy, and even these operated with limited technical staff and modest infrastructure support. The strategic plan itself had acknowledged this variation, noting that RCCs were in "varying states of start-up and implementation." Survey findings showed that 73% of respondents (147 out of 199) reported their institution had been involved in activities under the BSBS Strategic Plan (2021–2025). Among those who were unsure about their institution's involvement (n=27), a significant majority (92%) expressed a desire to participate in future activities under the upcoming BSBS Strategic Plan (2026–2030).

Despite these constraints, Africa CDC's leadership on BSBS was widely acknowledged as catalytic. The presence of a dedicated HQ team enabled the development of planning tools and regionally aligned technical materials. Several countries used these resources to guide national BSBS planning processes:

★ "Africa CDC gave us a roadmap template, and we used it to revise our national plan. That
was very helpful."

Beyond technical assistance, institutional readiness varied. Some stakeholders noted a lack of cascading of strategy materials and unclear implementation mandates:

*"The strategic plan is signed at higher level and not cascaded to implementers. Top management commitment also in question."

Also highlighted was distribution of information and participation in BSBS activities at national level limited to a select few.

*The information seems to circulate within a group of the select few. Our institution was not privy to the operationalisation of the strategy."

Survey feedback on inclusivity was mixed:

17%

of respondents (n=147) found BSBS activities to be very inclusive of gender, One Health stakeholders, and regional representation.

An additional 30% described them as mostly inclusive, while 32% said they were moderately inclusive.

In summary, while the establishment of a dedicated BSBS function at Africa CDC marked an important strategic shift, effectiveness was constrained by staffing gaps and uneven RCC functionality. These findings point to the need for more deliberate investment in operational capacity — particularly human resources — in the next strategic cycle (2026–2030).

Impact

Through its leadership under the BSBS Strategic Plan (2021–2025), Africa CDC contributed to measurable improvements in BSBS capacity across several AU Member States. These contributions were achieved through Africa CDC's strategic focus, coordination role, development of technical tools and provision of technical assistance, which supported implementation and monitoring at regional and national levels. However, while the BSBS initiative made a clear contribution, progress was also supported by efforts from other regional and international partners, including WHO, WAHO, and the Fleming Fund.

Joint External Evaluation (JEE) Findings

To assess potential contributions of the BSBS Strategy, the evaluation compared JEE scores for BSBS across two periods: Pre-strategy period (2016–2019) and the Post-strategy period (2023–2025).

Two indicators were used:

- P6.1 (now P7.1): Whole-of-government Biosafety and Biosecurity systems
- P6.2 (now P7.2): Biosafety and Biosecurity training and practices

In the Third Edition JEE Tool, the two indicators for P7 Biosafety and Biosecurity include; P7.1. Whole-of-government biosafety and biosecurity system in place for all sectors (including human, animal and agriculture facilities) and P7.2. Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture). These indicators were labelled P6.1 and P6.2 in the First and Second Editions of the JEE Tool.

According to available data, 5 of 55 Member States (9%) scored at least level 3 in both indicators during the post-strategy period, compared to 3 Member States (5%) pre-strategy, as shown in Figure 5. While modest, this reflects some improvement in core capacity alignment with IHR (2005).

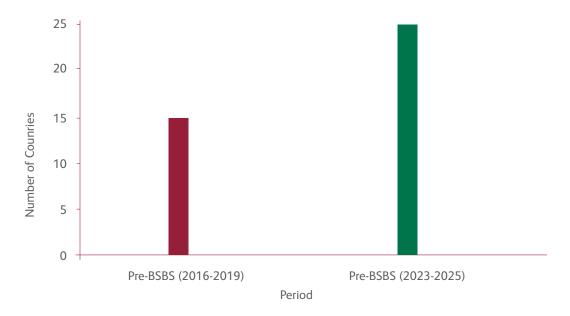


Figure 5: Countries with JEE score of at least 3 for both biosafety and biosecurity, pre- (2016-2019) and post-(2023-2025) Strategy period

However, interpretation of these results requires caution. The average score across Member States decreased slightly from 32% (2016–2019) to 21% (2023–2025), likely due to differences in reporting: only 34 countries had complete JEE data for both periods in the post-strategy phase. This limits comparability and may distort aggregate trends.

All Countries – Pre vs Post BSBS (Clustered Horizontal Bar Chart)

The clustered horizontal bar chart in Figure 6 compares average BSBS scores for all countries with available data. Most countries show a clear upward shift, with several moving from "no capacity" or "limited capacity" (levels 1–2) toward "developed capacity" (level 3) in line with International Health Regulations (IHR 2005) targets.

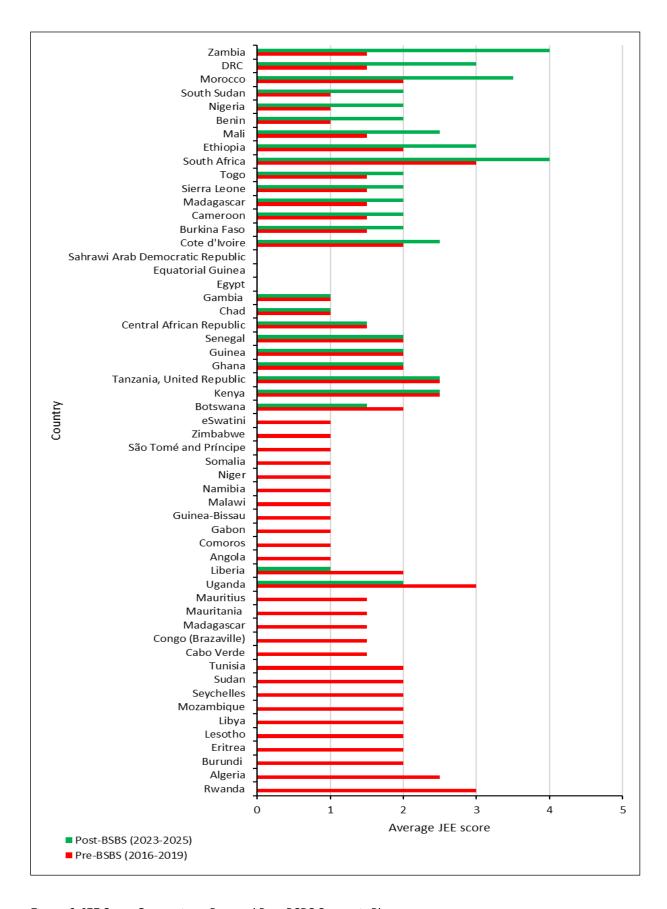


Figure 6: JEE Score Comparison: Pre- and Post-BSBS Strategic Plan

While BSBS improvements during this period were supported by Africa CDC's strategic contributions, they were not achieved in isolation. Countries also benefited from support provided through WHO country offices, regional mechanisms such as WAHO, and bilateral donor programs. The BSBS Strategic Plan added value by aligning tools and guidance with JEE indicators and offering coherent frameworks to Member States.

Top 10 countries by JEE Score Improvement

The chart in Figure 7 highlights the ten countries with the largest increase in average JEE scores between the two periods.

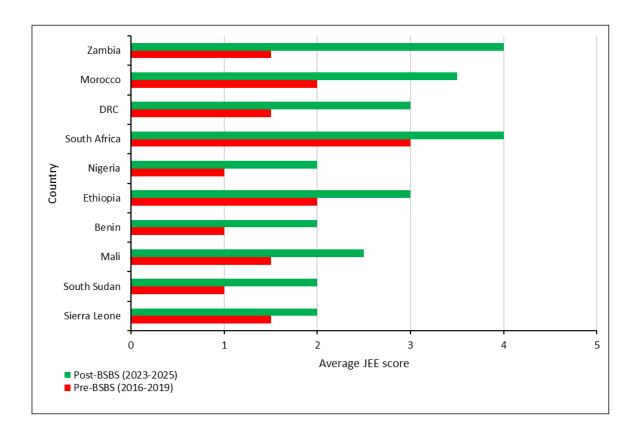


Figure 7: The Top Ten countries with the strongest average improvements in JEE scores

The strongest performers included countries actively engaged in Africa CDC-led legal mapping and development of roadmap for domestication of the Legal Framework. Zambia, South Africa, Burkina Faso and Sierra Leone all received training and assistance on legal mapping, drafting and review of legal instruments, national roadmap development, and domestication plans developed. South Africa also hosts a Regional Centre of Excellence, which was repeatedly cited as a catalyst for improved training and coordination and contributed to its high scores as articulated by a Member State Official:

"In 2017, we had three in both biosafety and biosecurity indicators now we had an improvement on the training indicator from three to four, specifically because of our activities in relation to the BBI. So, there's been direct impact...nationally then regionally. One of the big things is now having a formal training program and ability to develop capacity within our member states has brought about quite significant change across the region, yeah."

Despite progress in a few countries, the majority of Member States made limited gains. Among the 34 AU Member States with both pre- and post-strategy JEE scores, 72% showed no measurable improvement during the BSBS strategy period (2021–2025). This underscores the need for more targeted support to lower-performing countries, as well as strengthened mentorship, consistent follow-up, and better alignment of resources. While improvements were concentrated in a handful of Member States, the overall pattern points to an urgent need to scale support, promote equity, and institutionalize progress more effectively across the continent.

Africa CDC respondents noted:

*"But what we have noted is a number of countries have significantly improved in their scoring for biosafety and biosecurity using the JEE tool. That is the evidence we can put on the table."

Still, an implementor cautioned that the link between BSBS activities and outcomes should be interpreted with nuance:

*"From our end, what we can probably share are some of the key outcomes related to the activities that we planned during the Strategic Plan."

SPAR Findings: A Complementary Indicator

In parallel to the JEE, this evaluation reviewed the State Party Self-Assessment Annual Reporting (SPAR) Indicator C.4.2, which measures the presence of a national biosafety and biosecurity system. While this indicator is self-reported and subject to variability in interpretation, it remains a valuable proxy for institutional progress.

The data was compared across two periods: Pre-BSBS implementation: Average of SPAR submissions from 2018–2019 and Post-BSBS implementation average from 2023–2024. Only countries with data for both periods were included in the analysis.

Between 2021 and 2024: The proportion of countries reporting Level 3 or above for C.4.2 increased from 29% to 53%.

SPAR Score Comparison: Pre- and Post-BSBS Strategic Plan

The horizontal bar chart in Figure 8 shows average SPAR C.4.2 scores for countries before and after implementation of the BSBS Strategic Plan for each country with available data.

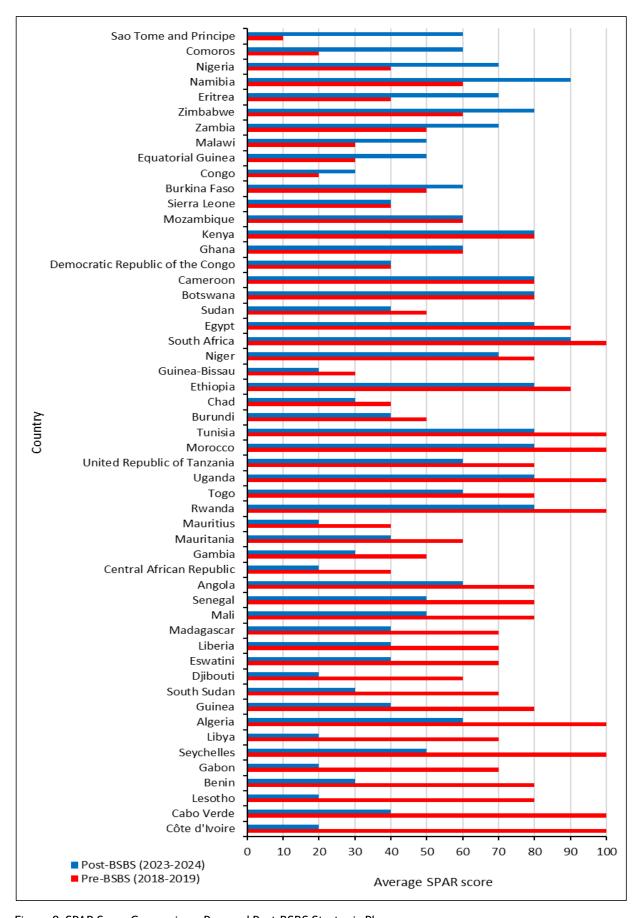


Figure 8: SPAR Score Comparison: Pre- and Post-BSBS Strategic Plan

While SPAR Indicator C.4.2 was included to assess progress in institutionalizing national BSBS systems, a notable observation was that several countries reported lower average scores in the post-strategy period (2023–2024). This does not necessarily indicate a regression in capacity. In many cases, lower scores may reflect improved understanding of the scoring framework, more critical self-assessment, or changes in reporting practices and personnel. Thus, SPAR scores offer meaningful insights and should be interpreted as one piece of evidence, triangulated with JEE scores and qualitative input for a fuller picture of system performance.

Top 10 Countries by SPAR Score Improvement

These countries demonstrated the strongest improvements in SPAR scores post-BSBS as shown in Figure 9.

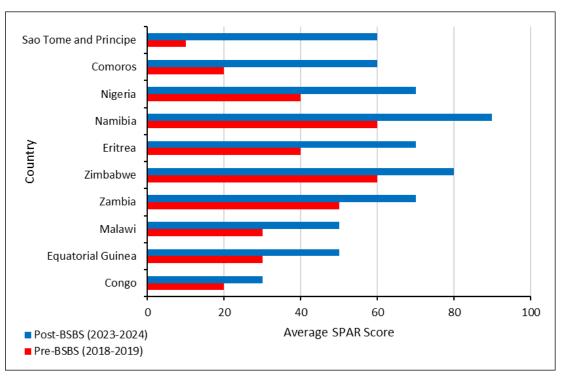


Figure 9: The Top 10 countries by SPAR score improvement after the BSBS Strategic Plan

Countries such as Zambia and Zimbabwe were among the top improvers. Both had received BSBS legal mapping support, drafting and review of legal instruments, national roadmaps as well as domestication plans developed for the BSBS Legal Framework. The BSBS Strategic Plan contributed meaningfully to strengthening BSBS systems, particularly in countries that engaged in legal domestication, regional training, and Africa CDC-supported TWGs. However, progress was uneven, and many Member States made limited gains. In order to close these gaps, the next strategy should prioritize low-performing countries, enhance partner coordination, and institutionalize mentorship and legal harmonization support.

*Countries that engaged actively with BSBS tools and technical assistance showed measurable gains in biosafety and biosecurity preparedness. Where engagement was limited, progress remained flat."

A senior respondent further emphasized the long-term nature of institutional capacity development:

"This is a marathon, not a sprint... there's been an increase in capacity based on the feedback that we've received, and we look forward to seeing how the strategy continues to move forward."

Other stakeholders described political uptake:

*"It helped build political will... now ministers know biosafety and biosecurity are critical for health security."

Sustainability

Stakeholders expressed measured optimism that the BSBS Strategic Plan (2021–2025) laid the groundwork for long-term institutional sustainability — particularly through the establishment of Africa CDC-led coordination structures, regional training hubs, and legal frameworks. However, most emphasized that sustainability will depend on continued technical support, national integration, and predictable funding. Survey findings support this cautious outlook where 76% of respondents (n=147) believed that BSBS improvements made under the strategy are likely or very likely to be sustained. Yet only 3% reported that their institutions had fully adopted the regional BSBS standards — suggesting that institutionalization remains a challenge.

A key constraint was the limited availability of funding. Only around half of the planned budget was secured during the strategy period. As mitigation, Africa CDC mobilized additional external resources, from World Bank, CEPI, and Africa CDC internal funding, which covered operational gaps and supported core coordination activities in addition to the core funding from Global Affairs Canada under the G-7 countries led Signature Initiative to Mitigate Biological Threats in Africa (SIMBA) initiative.

Stakeholders emphasized that sustaining BSBS gains will require embedding BSBS into national systems — including public health and budgeting frameworks, dedicated technical teams, and formalized TWGs in each Member State. They also underscored the need for continued Africa CDC coordination and peer support. While early progress was noted, stakeholders agreed that full consolidation will demand phased national integration, long-term planning, and consistent partner engagement.

Table 11: Summary of Achievements and Opportunities for Improvement and Strategic Implications for Priority Area 1

Achievements	Opportunities for Improvement and Strategic Implications
✓ BSBS Strategy adopted and used as a guiding document by Member States	Support deeper integration of BSBS into national systems, regulatory frameworks, and public health budgets
✓ Africa CDC planning tools and templates applied in roadmap and SOP development	Expand follow-up mechanisms and provide targeted technical assistance to reinforce national-level implementation
✓ Improvements in JEE/SPAR scores linked to BSBS rollout	Eleverage lessons from high-performing countries to support peer learning and strategic uptake across regions

Challenges:



Limited technical staffing and follow-up from Africa CDC Secretariat Uneven implementation across Member States

Incomplete integration of BSBS into national systems

8.2.2 Priority Area 2: Establishment and operationalization of five (5) multisectoral and multi-expert RBB-TWG and a continental TWG

Africa CDC developed a continental TWG to coordinate the implementation of the BBI. The continental TWG accelerated and optimized BSBS 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 Regional Biosafety and Biosecurity-Technical Working Groups (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 were established and operationalized.

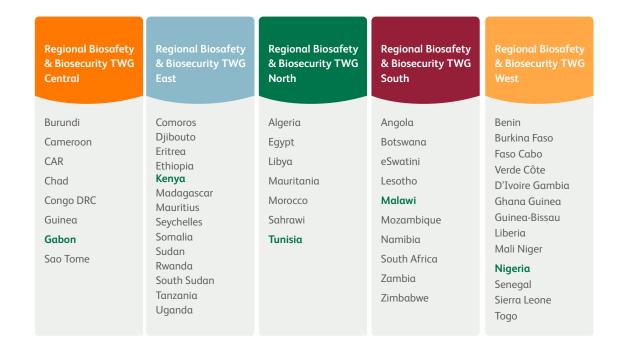


Figure 10: The 5 Regional TWGS operationalized during the 5-year strategy (Green denotes the Chair of the TWG during the strategy period)

Effectiveness

The establishment and operationalization of the five Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) was widely recognized as a major structural achievement of the BSBS Strategic Plan. These TWGs were consistently identified by stakeholders—including Member States, RCCs, technical partners, and development agencies—as foundational platforms for regional coordination, joint planning, and implementation of BSBS activities. Their creation marked a major step forward in establishing continent-wide structures to support biosafety and biosecurity.

"Obviously the structure of the technical working groups is relatively new for Africa CDC, but for us, it's been really important...we're leveraging the Africa CDC partnership to enhance biosafety and biosecurity capabilities across the region...We would not have a skeleton to do that if Africa CDC had not invested in the establishment of this regionally distributed network of technical working groups." — Development Partner

TWGs were not only present in all five regions but also functionally active. Stakeholders praised the TWGs for promoting peer learning, sharing technical experiences, and fostering regular cross-country exchange.

*"Each region has a Regional Technical Working Group for the coordination of biosafety and biosecurity within that particular region." — Eastern RBB-TWG Member

The TWGs were also widely seen as source of information and updates from the BSBS space by participants

*"I think if you ask me, we have had the greatest impact on the technical working groups. Because at that level, you are able to get first-hand information what is happening at various countries." — Western RBB-TWG Member

The TWGs were also viewed as platforms for experience and sharing and co-creation of region and country specific solutions

"The regional TWGs were really, really effective in bridging the gap in terms of information sharing... from the presentations that were done by each country, they really managed to share how the challenges they were facing, the different opportunities that they saw and even future endeavours in terms of improving biosafety and biosecurity." — Southern RBB-TWG Member

Survey results supported these findings:

86.4%

of respondents had participated in RBB-TWG meetings. Of those, 97% found the TWG engagements useful for strengthening coordination—with 30.4% rating them "very useful" and 37.6% as "mostly useful."

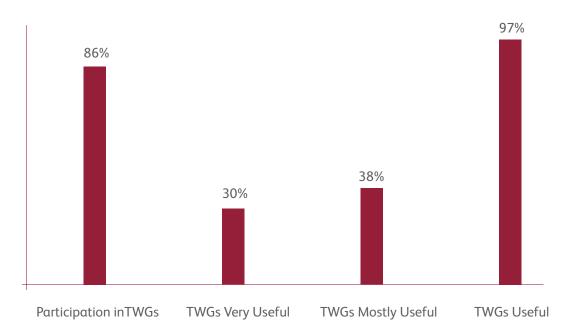


Figure 11: usefullness and participation TWGs meetings by respondents

The survey purposively targeted individuals directly involved in the BSBS Strategic Plan (2021–2025), such as members of TWGs and trained professionals. While this ensured responses from informed stakeholders, it may also introduce selection bias, as more actively engaged institutions were more likely to respond. As such, findings may not fully reflect institutions less involved in the strategy. TWG meetings provided structured forums for country updates, expert presentations, and cross-learning:

 \mathscr{T} "We always have agenda within our meetings where we have country reports... I can sit in my country and I know what is happening in Togo, Mali, Niger... it really helped in capacity building within the West African sub-region."

TWGs also played a critical role in raising awareness and advancing multisectoral participation:

"There's more buy-in and awareness when it comes to the program because every sector has a role... those people are nominated backed by authority and tasked to report back to their ministries."

In some cases, effective TWG coordination was linked to the early uptake of tools such as the AU legal framework:

"The reason why our Member States are taking on this challenge is the benefits or the positives that we are hearing from other countries. That's why when I talked about the regional TWGs and the national TWGs... the issue of information sharing is what is driving the uptake of this initiative."

TWG effectiveness extended into subnational coordination, with some Member States establishing national and even provincial technical working groups modelled after the regional structure:

*"We have a national technical working group and we have 10 provinces in Zambia. Each province has a provincial BSBS technical working group led by the provincial biomedical scientists."

Remaining Gaps in Effectiveness

 Uneven TWG engagement: Participation was inconsistent across countries and sectors. Some countries lacked strong representation or sustained involvement.

*"There is always the fact that to belong to the TWG, you need to be selected... and not all countries have strong representatives or are consistently involved."

• Lack of guidance on sustainability: Respondents called for a clearer framework for TWG operation.

*"We need a framework and maybe guidance... the step-by-step how to establish and sustain a TWG is not necessarily spelled out."

Having TWGs members officially nominated by their respective Ministries and the TWG officially recognized would improve its functionality.

These findings suggest that while TWGs were a cornerstone of the BSBS implementation strategy, strengthening their formalization, sustainability, and national-level consistency will be critical for future effectiveness.

Implementation

A key implementation strategy under the BSBS Strategic Plan was the establishment and operationalisation of all five Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) as regional coordination hubs, achieving full geographic coverage. These groups convened technical experts from across sectors and countries to guide implementation, share lessons, and strengthen alignment with the Africa CDC's strategic vision.

*"The TWGs were 100% implemented and succeed — they created the structure for sharing information and coordination that was missing before."

Of the survey respondents, 75% (n=195) reported participating in the RBB-TWGs, suggesting that the coordination mechanisms under this priority area were widely operationalized. According to the Strategic Plan, each TWG was expected to meet quarterly — comprising three virtual meetings and one face-to-face meeting per year. According to project reports, 75 virtual and 25 physical TWG meetings were conducted by 2025, meeting the planned frequency and geographic coverage targets across all five regions. TWGs were regularly involved in reviewing tools, identifying country priorities, and sharing implementation experiences. As one official involved in the BSBS implementation remarked:

*"The regional biosafety and biosecurity technical working groups...have all been operationalized across the five regions of Africa and have been able to meet consistently, virtually and face to face during the five-year period."

TWG meetings enabled not only technical coordination but also trust-building between national focal points across human, animal, and environmental health sectors.

Over time, this regional model was replicated at national and subnational levels. In response to Africa CDC's recommendation, many Member States established National TWGs to localize coordination efforts and sustain the momentum of the regional strategy. These structures were noted to enhance uptake of BSBS activities, especially in countries with regular meetings and broad multisectoral participation.

*"One of the things that supported the quick uptake was in-country structures that allowed the activities to thrive... In Member States where we have strong technical working groups that meet frequently in the spirit of the program, there was better uptake."

Several Member States adopted a multilevel coordination structure, extending beyond national bodies:

*We have a national technical working group and we have 10 provinces in Zambia. Each province has a provincial BSBS technical working group led by the provincial biomedical scientists."

The multisectoral composition of these TWGs—drawing from public health, animal health, environment, and security sectors—was a defining feature, strengthening One Health coordination:

"One of the key things that the technical working group has managed to do is build awareness... every sector has a role. Those people are nominated, backed by authority, and tasked to report back to their ministries."

TWGs managed to produce and disseminate several technical outputs, including guidance notes and implementation templates. These were used by Member States to align national activities with regional priorities:

 \checkmark "Once the TWG shared the template, we adapted it nationally."

Africa CDC provided capacity-building and technical support to TWGs. However, implementation quality varied due to internal capacity gaps. Staffing shortages at Africa CDC and within RCCs were noted by several respondents as affecting the timeliness and consistency of coordination and follow-up:

*"There are few staff to follow up... they do their best, but the scope is too wide for the team currently in place."

Implementation challenges were also reported:

- Some countries lacked formal TWG structures even by the end of the strategy period.
- Several TWGs operated informally without legal anchoring or dedicated funding.
- Participation varied by region and sector, and virtual engagement was less impactful than in-person collaboration:

*"You can't compare the impact of in-person meetings to online. To really build ownership, the meeting should not just be one day."

There was a clear call for Africa CDC to develop more structured guidance on how to establish, operationalize, and sustain national TWGs:

*"We need a framework and maybe guidance... the BBI talks about the importance of TWGs, but the how—the step-by-step—is not necessarily spelled out."

While the establishment of TWGs was widely recognized as a significant implementation achievement, several respondents noted gaps in how these structures functioned operationally. Despite regular meetings and broad participation, some stakeholders described a lack of clarity on expected outputs and follow-up actions:

Coordination within the technical working group, I think ambition should be better. What I mean by that is although it is set up and I joined a number of meetings... I think sometimes the meetings are not as effective as I expected them to be. There should be clear agenda... it should end with action points, timelines, things that the countries are supposed to do."

The absence of mechanisms like key performance indicators (KPIs) or post-meeting accountability was also raised:

"Quarterly meetings are held. Reports are given. But I have that thinking that the TWG could do more. Most of the times things are ending with a lot of things said. When we get back, they are not implemented or measured properly... There should be KPIs for these technical working groups."

Some Member States also reported challenges in operationalizing national TWGs, which were seen as critical to embedding biosafety and biosecurity systems domestically:

"We made an attempt to set up a national TWG for biosafety biosecurity, which would have been another big plus for us if we had succeeded... I'm looking at a situation where we really have a TWG, a national technical [group] that, for me, essentially will kick-start every other system that is going to make sure that we are well governed, we are coordinated, we are able to even achieve the goals of the Africa CDC program."

In addition, some stakeholders expressed frustration with the limited tangible outcomes of regional collaboration, noting a gap between meetings and actionable progress:

*Considering that for five years, we've been meeting as a regional organization... Let's talk about collaborations in terms of research. It's almost zero. I don't think the regional collaboration has metamorphosed anything."

These perspectives reinforce the importance of strengthening national structures, embedding measurable objectives into TWG coordination efforts, and improving the translation of regional dialogue into national implementation and impact.

Impact

The TWGs contributed to tangible downstream changes by enabling countries to adapt Africa CDC-led guidance into national strategies, policies, and institutional actions. In several Member States,

TWG engagements helped catalyze the establishment of national TWGs, increased multisectoral coordination, and improved visibility of biosafety and biosecurity among policymakers.

"We made an attempt to set up a national TWG... a national technical [group] that, for me, essentially will kick-start every other system... so we are well governed, coordinated, and able to achieve the goals of the Africa CDC program."

Member States began taking ownership of BSBS coordination structures, with examples of countries forming TWGs at national and subnational levels that mirrored the regional design.

Countries began adapting TWG outputs for instance, one Member State adapted the TWG-developed biosafety SOPs for its emergency response protocols during a laboratory containment drill. Increased peer pressure and regional visibility also appeared to accelerate uptake of strategic initiatives such as the AU legal framework:

*"The reason why our Member States are taking on this challenge is the benefits or the positives that we are hearing from other countries."

The TWGs contributed meaningfully to cross-country alignment and strengthened national BSBS actions. The initial TWG structures laid the groundwork for the full BSBS Strategic Plan, ensuring local implementers had a voice from the outset:

"Those initial technical working groups were instrumental in kind of building the foundation of that eventual five-year plan. It was... the voices of the people who would have to implement the work."

Stakeholder feedback indicated that the TWGs not only enhanced collaboration but also enabled timely problem-solving and better coordination with Africa CDC:

*Given the cross-cutting nature of biosafety and biosecurity, this greatly contributed towards better coordination across the Member States."

While concrete joint regional outputs were still limited, the TWGs helped embed institutional memory and momentum for continued investment, especially in countries with consistent participation. However, the anticipated long-term outcomes — such as sustained research collaboration, harmonized cross-border procedures, or formalized regional policy alignment — were only partially realized.

*Let's talk about collaborations in terms of research. It's almost zero. I don't think the regional collaboration has metamorphosed anything."

This suggests that while the TWGs contributed to important shifts in visibility, ownership, and structural alignment, their broader strategic impact could be deepened through clearer mandates, integration into national systems, and mechanisms for collaborative outcomes beyond coordination.

Sustainability

The TWG model is widely regarded as an important legacy of the BSBS Strategy. While the TWGs were operational and valued during the strategy period, stakeholders raised persistent concerns about their sustainability beyond the life of the plan.

Challenges to Sustainability

A major barrier to continuity was the TWGs' reliance on external funding to support meetings, logistics, and coordination. Some regions experienced irregular scheduling of TWG meetings due to this funding dependency, and participation was often contingent on donor support.

In addition, many TWG members served in a voluntary capacity without honorarium or recognition, which led to participation fatigue and weakened ownership. Several members expressed a lack of formal institutional support from their home agencies, further reducing their motivation to engage actively in TWG activities.

TWGs were also not uniformly embedded in RCC or national governance frameworks. Without formal mandates or legal recognition, the sustainability of their structure remains vulnerable.

Stakeholders also raised concerns about the limited empowerment and decentralization of TWG operations, noting that the model, while effective in convening, had not yet matured into a mechanism capable of mobilizing regional support and technical assistance:

"I think the technical working groups have done well. That is to say, I don't think they are empowered to support the Member States who are within their countries... The coordination is centralized... the Secretariat is overwhelmed... It's not possible for one or two people to serve so many countries. We need to empower the TWGs, train them to play an advocacy role, support other Member States, and fast-track meetings even in the absence of the Secretariat."

Opportunities for Institutionalization

Despite these challenges, stakeholders described the TWG model as one of the most promising and innovative features of the strategy. In some RCCs, discussions were already underway to integrate TWGs into regional health governance platforms. Others recommended that TWGs be incorporated into Africa CDC's core programming with predictable budget lines for coordination and follow-up. Stakeholders also advocated for national-level actions to formalize TWG roles and responsibilities, including domestic funding allocation, official appointment letters, and linkage to national biosafety and biosecurity policies.

*We should not lose what was started. With small support, these TWGs can become a formal part of national systems."

*"If they are reflected in the national plans and budgets, even when donor funds reduce, we can continue."

Some TWGs had already made early strides by contributing to national training programs or supporting the rollout of AU-endorsed tools. However, these examples were not widespread, and more intentional planning is needed to align TWG activities with national legislative and workforce systems.

Path Forward

Stakeholders emphasized the need to institutionalize the TWGs within Africa CDC and RCC governance structures and to ensure operational costs are integrated into core program budgets. Stronger national ownership—through official mandates, incentives for members, and integration into multisectoral platforms—was seen as essential for sustaining TWG functionality in the next strategic cycle.

Africa CDC was encouraged to issue a formal TWG institutionalization framework and to promote the adoption of TWG outputs (e.g., training curricula, SOPs, coordination templates) into Member States' health policies and systems. Overall, while the TWGs demonstrated clear utility and regional coordination value, their long-term viability will depend on predictable funding, policy integration, and shared accountability among all partners.

Table 12: Summary of Achievements and Opportunities for Improvement and Strategic Implications for Priority Area 2

Achievements	Opportunities for Improvement and Strategic Implications
✓ All five RBB-TWGs established and operationalized across all regions	Institutionalize TWGs within national governance structures with formal mandates and RCC health coordination platforms
✓ 100 TWG meetings held (75 virtual, 25 in-person)	Ensure Africa CDC staffing and resources are scaled to support coordination
✓ TWGs viewed as effective for multisectoral coordination and peer learning	☑Integrate TWG operations into Africa CDC core program budgets
✓ TWGs contributed to tool development and alignment of national actions	Provide formal mandates and incentives to sustain TWG engagement
✓ TWG structure replicated in some MS at national and subnational levels	② Increase national ownership through appointment letters, funding commitments, and policy links
✓ TWGs facilitated uptake of AU legal framework and other BSBS initiatives	Empower TWGs to support Member States through technical assistance, peer exchange, and advocacy roles
✓ TWG model recognized as a durable legacy of the BSBS strategy	Formalize training, coordination templates, and tools into national legislation and HR systems
	Introduce formal performance tracking of TWG functionality



8.2.3 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 prior to the BSBS Strategy (2021-2025), 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. In addition, 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.

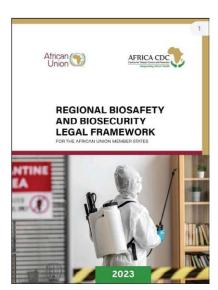
MS recommended that Africa CDC coordinate the development of a regional BSBS Legal Framework. The BSBS Legal Framework served two purposes: first, it was used by a MS to guide review of existing legal instruments to more fully understand its existing legal capacity to support BSBS; second, the BSBS Legal Framework identified ways that a MS legal instruments could be amended to increase support for BSBS oversight mechanisms.

Effectiveness

The development and adoption of the African Union BSBS Legal Framework was widely recognized by stakeholders as one of the most significant accomplishments of the BSBS Strategic Plan (2021–2025). The process, led by Africa CDC, followed a consultative and region-wide approach that ensured the participation of legal experts, technical specialists, and Member State representatives. According to Africa CDC records, 84% of AU Member States took part in one or more phases of the framework's development.

"The key milestone firstly was adoption of the Africa Union legislative framework for biosafety and biosecurity, which involved all of us... every region looked at it at different times and finally came up with this document."

The final framework was adopted through multiple levels of AU endorsement: first by the Specialized Technical Committee (STC) for Health, Population and Drug Control in June 2022, followed by recognition by the AU Heads of State Summit in July 2022, and further endorsement by the STC on Justice and Legal Affairs in November 2022. The framework is now publicly accessible via the Africa CDC website.



Domain 1

Authorization of Lead Entity Responsible for Regulating Biosafety and Biosecurity

Domain 2

Development of National Standards for Biosafety and Biosecurity

Domain 3

Authority for Biological Risk Assessment of Agents and Toxins

Domain 4

Regulation of Laboratory and Facility Level Requirements for Handling Agents and Toxins of Concern

Domain 5

Education, Training, and Human Resource Requirements for Personnel who Possess, Use, Store, or Transfer Agents and Toxins of Concern

Domain 6

Transfer, Storage, and Disposal of Agents and Toxins of Concern

Anticipated Challenges and Proposed Solutions

Figure 12: The Regionally endorsed BSBS Legal Framework under domestication by Member States

Beyond its technical content, the framework was regarded not only as a technical tool but also as a political lever for national-level engagement:

*"We managed to have a regional legal framework to oversee the legislation aspect in each member state in African continent. The documents were approved by all specialized technical committee of the African Union and the head of states."

The development process itself was viewed as inclusive and well-structured, which contributed to the framework's legitimacy and alignment with regional realities. The active role of the TWGs in reviewing draft content, validating versions, and facilitating national feedback loops was widely appreciated.

*"When we talk about technical working groups, it is very much inclusive... lawyers, civil society... all key players."

In particular, the inclusion of legal professionals, civil society organizations, and multi-sectoral government representatives within the TWG membership helped ensure that the resulting framework was both contextually relevant and grounded in diverse regional legal traditions.

In sum, the BSBS Legal Framework is considered a cornerstone output of the strategy, with a strong foundation in participatory development, political endorsement at the continental level, and technical relevance for guiding national legal reform. The clarity of its structure, wide recognition by AU organs, and broad-based participation during development collectively reinforce its credibility and effectiveness.

Reinforcing Global Alignment

The AU BSBS Legal Framework was not only seen as a technical tool for regional coordination, but also as a mechanism for aligning Member States with key international obligations. Stakeholders emphasized that the framework supports legal and policy coherence with the Biological Weapons Convention (BWC), the International Health Regulations (IHR 2005) and the Cartagena Protocol on Biosafety.

This alignment reinforced the framework's strategic relevance and legitimacy, providing Member States with a structured pathway to meet their global commitments. In this regard, the AU framework helped bridge national and international regulatory expectations, strengthening Africa's contribution to global biosecurity governance.

Implementation

Despite the strength of the AU BSBS Legal Framework, national-level implementation has progressed unevenly across Member States. By 2025, 8 of the 10 targeted Member States (80%) had received training and technical assistance from Africa CDC on legal mapping, drafting, and review of legal instruments. Additionally, 7 of the 12 targeted Member States (58%) had developed national roadmaps for domestication of the Framework, while only 2 (17%) had developed domestication plans, as shown in Figure 13. The Member States include; Zambia, Sierra Leone, Lesotho, Botswana, Zimbabwe, Burkina Faso, South Africa and Eswatini.



Figure 13: Member States progress on the adoption if the AU Legal Framework

Africa CDC's legal mapping exercises and checklist tools helped clarify what needed to be aligned and monitored:

*"They're checking... it's like a checklist to see whether they have what's included in the domains... ensure that there is compliance with the legislation for biosafety, biosecurity."

Africa CDC's legal mapping tools and domestication checklist enabled countries to benchmark their existing laws against the Framework's six domains, perform legal gap analyses, and prioritize areas for reform. These tools were particularly valuable in contexts where BSBS mandates were fragmented or unclear.

*"The biggest challenge [in] domesticating is identifying a lead entity for biosafety... It falls in different ministries — Health, Defence, Vice President's Office."

In several countries, overlapping mandates and fragmented responsibilities across sectors created bottlenecks for implementation. Stakeholders reported that in some cases, inter-ministerial working groups stalled due to the absence of a designated lead agency and lack of high-level coordination.

"Our legal status is currently fragmented. We have different agencies implementing biosafety and biosecurity within their own statutes — not in a holistic manner."

However, some Member States demonstrated notable progress. Lesotho, for example, was widely cited as a positive case where domestication was actively pursued and resourced:

*"Lesotho has established a strategic plan... secured funding, conducted trainings, and developed a roadmap for domestication of the legal framework."

Lesotho's progress was attributed to a combination of high-level political will, clear designation of a lead ministry, and external donor support — factors that could serve as a model for replication in other countries. From the survey findings, 71% of respondents (n=147) were aware of the AU BSBS Legal Framework, while 50% of respondents (n=103) indicated that their institutions had actively engaged in domestication-related activities. Although encouraging, this indicates that many institutions remained unaware or uninvolved in the process — a gap that highlights the need for further outreach and operational planning.

Implementation progress was uneven across regions, with West Africa reporting greater legal mapping completion than Central Africa. Southern Africa (6/8) showed relatively greater progress in legal mapping and roadmap development, with at least five countries making tangible strides. This was often attributed to clearer institutional leadership, political commitment, and regional support. In contrast, some countries in Central and North Africa faced delays due to institutional fragmentation and limited technical coordination. Some regions faced challenges with aligning diverse national legal traditions, but regional workshops helped achieve consensus.

Key Insight

Maintaining momentum will require continued Africa CDC coordination, especially in supporting multisectoral engagement, promoting domestication checklists, and offering legal advisory services. Targeted technical assistance and governance reform support will be critical in helping countries overcome structural fragmentation and build durable legal systems aligned with the AU Framework.

Impact

At the time of evaluation, only a few Member States had completed or initiated formal domestication of the AU BSBS Legal Framework. By 2025, 7 of the 12 targeted countries (58%) had developed national roadmaps for domestication, and 8 countries had formally initiated processes, a meaningful milestone that signalled growing political and institutional commitment. At the time of the evaluation, only 8 of the 55 African Union Member States (14.5%) had formally initiated the domestication of the BSBS Legal Framework.

More significantly, the domestication process served as a catalyst for institutional introspection and inter-ministerial coordination. In many countries, it marked the first time that BSBS had been addressed across ministries in a coordinated manner:

*"What worked well for us was the inclusion of legal experts from the Ministry of Agriculture, Health, Defence, and even Parliament."

In at least 12 countries, the AU framework served as a benchmark for revising public health and biosafety legislation. Several Member States reported using the AU framework to guide the review of existing sectoral laws, helping to align responsibilities across ministries. Legal drafters in six countries indicated improved capacity to conduct gap analyses and align statutes with the framework's seven domains after attending AU-led workshops.

*They're checking... it's like a checklist to see whether they have what's included in the domains... ensure that there is compliance with the legislation for biosafety, biosecurity."

In some instances, the roadmaps catalyzed institutional innovations, such as the formation of multisectoral biosafety committees that were subsequently integrated into national emergency preparedness structures. The presentation of domestication plans to Parliament in countries like Zimbabwe and Lesotho was also seen as a critical indicator of political buy-in.

Regional organizations, such as the Economic Community of West African States (ECOWAS), began referencing the AU Framework in their internal guidance documents, suggesting early traction at the sub-regional level.

While full legislative domestication remains incomplete in most countries, the process has already begun to shift institutional behaviour, promote inter-ministerial collaboration, and embed BSBS within broader national health security and legal reform agendas.

These are early signals of systemic impact, which, if nurtured, could lay the groundwork for deeper alignment with international obligations in the next phase of the BSBS strategy.

Sustainability

While early impacts were evident in roadmap development and inter-ministerial engagement, stakeholders recognized that long-term sustainability would depend on national legal integration, political commitment, and institutional continuity.

A BSBS legal framework, once embedded in national statutes, offers strong potential for long-term sustainability. However, the complexity of legal harmonization, overlapping mandates across ministries, and the need for high-level political buy-in remain significant hurdles. Several informants noted that the scale of the reform discouraged some countries from progressing beyond initial consultations.

 \checkmark "But it needs a lot of, a lot of, a lot of, a lot of meeting... to get a legislation or to commit, you know, it's very hard. So, they need to get that legislation in our country... it needs a lot of meetings, a lot of experts... that is the only challenge. We can do it, but it's a lot of challenge before." – Respondent from Eastern RCC

Even in the face of these challenges, early adopters illustrated that incremental progress was not only feasible but necessary. The experience of Zimbabwe highlighted a pragmatic, step-by-step approach to legal domestication.

"I think the challenge is thinking that it cannot be done... But baby steps need to be taken...

That is what we are doing in Zimbabwe."- Respondent from Southern RCC

In Sierra Leone and Lesotho, initial legislative reviews have already been tabled for inter-ministerial input, and coordination mechanisms have been proposed for institutionalization. These emerging practices point to a growing understanding that legal reform is a gradual but achievable process. Some countries proposed integrating biosafety provisions into broader legislative frameworks—such as public health or disaster preparedness laws—as a sustainability enabler. This approach could reduce legal fragmentation and help embed biosafety and biosecurity within long-term institutional mandates.

At the continental level, stakeholders emphasized that sustaining the momentum of legal alignment will require continued technical support, political advocacy, and Africa CDC's convening power in the next strategy phase.

*"Stakeholders noted that sustaining the momentum of legal alignment would require Africa CDC's continued convening role and technical support in the next strategy phase."

Additionally, embedding the AU Legal Framework into Africa CDC's strategic programming and aligning it with broader AU policy instruments was seen as critical for long-term uptake.

Risks to sustainability include persistent conflicts in ministerial mandates (e.g., between Health, Defence, and Environment), limited central coordination bodies, and high dependency on donorfunded technical assistance.

To move from momentum to measurable results, the next strategy will need to prioritize:

- Designation of national lead institutions for BSBS law
- Institutionalization of legal task forces or TWGs
- Incremental integration of the AU framework into national statutes
- Long-term financial and technical support from Africa CDC and RECs

Sustained support—financial, political, and technical—will be essential to transform this early momentum into lasting legal and institutional systems. Sustaining the momentum generated by the AU BSBS Legal Framework will require a concerted effort from Africa CDC and Member States alike. Stakeholders emphasized the need for Africa CDC to maintain its convening power and provide ongoing technical assistance during the next strategic cycle. This continued engagement will be critical not only for advancing national legal reforms but also for embedding BSBS into broader health security frameworks and ensuring that early progress translates into long-term legal, institutional, and operational sustainability.



Case Study: Legal Framework Domestication in Zimbabwe

Zimbabwe's experience with the domestication of the AU BSBS Legal Framework provides a practical example of stepwise national adaptation. At the outset, the country faced significant fragmentation, with BSBS responsibilities dispersed across multiple ministries

and statutory instruments.

Recognizing the need for a more coherent legal architecture, Zimbabwe formally requested technical assistance from Africa CDC in 2023. In early 2024, Africa CDC responded by facilitating a legal mapping process and convening a domestication workshop. A key enabler of progress was the meaningful engagement of legal experts from multiple ministries and the Parliament.

*"What worked well for us was the inclusion of legal experts from the Ministry of Agriculture, Minister of Health, Minister of Defense, and even from the Parliament."

The legal mapping exercise enabled stakeholders to identify and assess relevant laws already in place, while the workshop catalyzed inter-ministerial dialogue. Participants noted that this process significantly improved visibility into existing statutes and highlighted opportunities for legislative harmonization.

"We did the desk review... then a first workshop on domesticating the legal framework... we opened our eyes to see which statutes actually speak to biosafety and biosecurity."

Following the workshop, Zimbabwe established a cross-ministerial legal task force and drafted an action plan to consolidate BSBS mandates into a single statutory instrument. This represents a critical institutional shift toward legal alignment, although full domestication remains in progress.

Stakeholders emphasized that while the technical process has been constructive, securing Cabinet-level or presidential endorsement will be essential for final approval and long-term institutionalization. Zimbabwe's approach demonstrates that incremental progress, grounded in inter-ministerial collaboration and targeted technical guidance, can create momentum and lay the groundwork for sustainable legal reform. Its experience may serve as a replicable model for other Member States facing similar challenges of fragmented governance in biosafety and biosecurity legislation.

This case highlights the importance of early technical engagement, political support, and cross-sectoral collaboration in advancing the domestication of the AU BSBS Legal Framework.

Table 13: Summary of Achievements and Opportunities for Improvement and Strategic Implications for Priority Area 3

Key Achievements	Opportunities for Improvement and Strategic Implications
✓ The continental/Pan African BSBS Legal Framework was developed, validated, and endorsed at the AU level by legal and Heads of States	Accelerate technical legal support for national roadmap development to guide the domestication process and legislative reforms
✓ Legal mapping and gap analysis exercises were successfully conducted in 8 Member States	Provide sustained legal and policy advisory support, including training and technical assistance for legal drafters and policymakers and guide them to develop drafting instructions and cabinet papers
✓ Training of legal drafters and roadmaps developed in 7 Member States	Promote coordinated inter-ministerial engagement, with clear designation of lead institutions for BSBS governance
✓ Early stages of legal domestication in 2 Member States	☑Institutionalize the BSBS legal framework within national legislative and regulatory systems, ensuring alignment with constitutional, public health, Agriculture and Animal health, environmental, and security laws
	Monitor and document legal domestication progress to inform AU and Member State reporting, strategic BSBS investment and leverage early adopters as peer-learning case studies
	Position Africa CDC as a continued convener and source of legal technical support in the next strategy phase
	©Encourage political advocacy and cross-sectoral dialogue to strengthen high-level buy-in

Key Challenges

- Inadequate national coordination structures for legal adoption and implementation
- Fragmentation of legal mandates across ministries, departments, and agencies
- Limited progress in achieving legal domestication milestones across most Member States
- Some Member States lacked clarity on which institution should lead the domestication process.
- Slow uptake of domestication due to competing legislative priorities, lack of inter-ministerial coordination and
- Africa CDC's approach of waiting for countries to request for technical assistance for adoption
 of BSBS Legal Framework was a major limitation. There was a need to be a little bit proactive for
 example through more high-level advocacy
- Political endorsement and national legal integration processes remain complex and under-resourced.

8.2.4 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 developed a regulatory and certification framework for high containment facilities. Benchmarks and regional standards of BSBS based on international requirements for compliance by high-level containment institutions (human, animal, and plant health) were 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 were used to award certification that is star 0 to star 5. Training of AU MS on the minimum standards were conducted through the established COE including training and certification of a pool of assessors.

Effectiveness

Africa CDC developed and rolled out a regional certification and assessment framework for institutions handling High Consequence Agents and Toxins (HCAT). The framework consisted of three core components: minimum biosafety and biosecurity standards, an assessment checklist, and a starbased certification rating model.





Componets 1 Minimum Standards for Biosafety and Biosecurity



Componets 2
Scored Standard
Assessment
Checklist



Componets 3
Recognition and
certification
Framework

Figure 14: The Regulatory and Certification Framework for Institutions Handling HCATs

These tools were designed to be regionally relevant, practical, and more feasible than previously available international models.

"It does seem like quite a few facilities are interested... there's this cadre now of trained assessors... it demonstrates a pool of expertise... that can really be used for other aspects of biosafety and biosecurity capacity strengthening across the continent."

One of the foundational steps under this framework was the training of a core group of implementers — institutional representatives from high containment laboratories — who were trained to understand the minimum standards, oriented on applying the checklist and preparing their institutions for certification. This helped build local understanding of the certification criteria and fostered demand and ownership for the process.

This was followed by the training of a pool of assessors, who were equipped to conduct evaluations using the Africa CDC-developed checklist. Together, these two groups formed the operational backbone for implementation of the framework at national and regional levels.

According to the BSBS Strategic Plan's intervention logic, the target was to certify 15 laboratories by 2025. By the end of the strategy period, the following results were achieved:

- 4 (27%) laboratories were assessed and certified
- 45 assessors were trained across 21 Member States
- 83 implementers were trained from 35 Member States

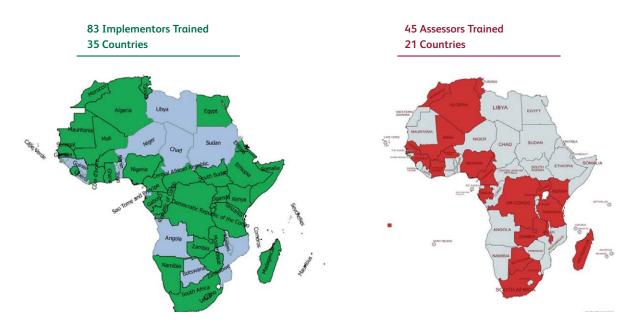


Figure 15: Summary of Assessors and Implementors of the Framework trained across the Region

*"Based on the training we have received; our institution was able to go through the assessment and become certified as compliant."

*"What we have noted is a great improvement in containment, especially in the BSL-3. We were not able to manage some of those practices before."

While the certification target was not fully reached, the results reflect early progress and indicate strong Member State interest and participation across regions. Respondents repeatedly described the framework as practical, achievable, and well-aligned to institutional realities.

*"Just knowing that that pool of expertise is there is already an accomplishment, I think." These developments point to a growing continental capacity to maintain and expand biosafety certification beyond the initial five-year strategy.

Implementation

The implementation of the Africa CDC regional certification framework was widely regarded by institutions and assessors as effective, timely, and professionally managed. While the process was technically rigorous, it was also designed to be adaptable, evidence-based, and supportive of institutional realities.

Africa CDC led and sponsored the full assessment process, including on-site evaluations, start-up briefings, and timely report delivery. Respondents consistently praised the efficiency and responsiveness of the assessment teams.

*"This is all sponsored which was great... I didn't have to go through too many bureaucracies to get it done."

The process also demonstrated a strong degree of contextual flexibility. While grounded in minimum standards and technical criteria, assessors took a risk-based approach to evaluating readiness. This allowed laboratories to justify certain adaptations as long as safety outcomes were achieved.

*"Some things that didn't meet the standard... we could prove effectiveness through proper risk assessments."

Assessment tools, including the checklist and star-rating model, were designed to guide institutional self-preparation prior to formal certification visits. This stepwise model helped laboratories gradually align with expectations, increasing ownership and readiness ahead of formal assessments.

The assessors trained by Africa CDC were central to implementation. Their presence across 21 Member States allowed certification efforts to be regionally distributed. Additionally, Africa CDC's coordination ensured that feedback from one certification round informed improvements in future rounds, particularly regarding logistics and report clarity.

Facilities that underwent certification were supported throughout the process — from initial engagement to post-assessment review. Some respondents noted that Africa CDC's communication and engagement helped reduce bureaucratic delays and fostered trust in the process. The precertification training of implementers also improved internal institutional coordination and readiness for assessment.

*"It was not just a checklist visit. It was a process where we got to understand where we were strong and where we needed to improve."

Despite the positive implementation experience, challenges included limited availability of assessors in some subregions, infrastructure readiness gaps in some laboratories, and the absence of structured national follow-up mechanisms after certification. These gaps were identified as areas for improvement in the next strategy cycle.

Impact

The Africa CDC-led certification initiative contributed to measurable improvements in biosafety and biosecurity practices across assessed institutions. Certified laboratories reported enhanced internal systems, stronger adherence to protocols, and growing confidence in their ability to manage high-consequence pathogens in line with regional standards.

Institutions that underwent certification shared evidence of improved infrastructure, revised standard operating procedures (SOPs), and strengthened internal compliance cultures. The tiered certification approach — including provisional scoring and opportunities for correction — helped laboratories refine their practices in real-time.

*"We were at three stars initially, but after providing clarification and additional documentation, we were upgraded to four stars."

The recognition provided by the Africa CDC certification was also seen as valuable for institutional credibility, research partnerships, and external funding opportunities. Laboratories noted that certification not only validated their operational readiness but also positioned them as reference facilities for regional or cross-border response.

 \mathscr{T} This certificate will help us a lot when it comes to research — especially if someone is bringing in a pathogen."

Even in institutions that had not yet completed certification, the rollout of the framework — including training of implementers and self-assessment using the Africa CDC checklist — triggered important changes. Respondents cited improvements in documentation practices, staff training, laboratory workflows, and procurement of biosafety equipment.

*"We have not been certified yet, but the checklist helped us audit our lab and identify areas we needed to upgrade, like our access control and waste handling."

The process also built internal momentum for safety culture transformation, prompting institutions to invest more in risk assessment, staff compliance monitoring, and interdepartmental coordination. At a continental level, the development of a cadre of assessors across 21 Member States was seen as a significant milestone. This pool of expertise now forms a resource base that can be mobilized to sustain and expand certification efforts beyond the initial BSBS strategy period. In some countries, these assessors were already supporting peer institutions, contributing to knowledge sharing and regionally anchored technical leadership.

Although the number of certified laboratories remained below target, the program's influence extended well beyond the formally assessed sites. The Africa CDC framework became a reference tool across

multiple Member States and contributed to harmonization efforts and readiness for national or international accreditation in the future.

Sustainability

The certification framework introduced by Africa CDC was widely recognized as a catalyst for institutional change and a shift toward performance-based biosafety culture. Institutions reported that the structured assessment process helped instill internal accountability and motivated continuous improvement. However, sustaining this momentum beyond the initial strategy period presents several challenges.

One of the key barriers to sustainability is the infrastructure readiness gap in many institutions. Facilities faced practical constraints in meeting some physical requirements outlined in the checklist — particularly where architectural features or local design standards conflicted with standard expectations.

"Our floor is jointed... that's Japanese earthquake design. We sent documentation from the contractor to explain why."

Africa CDC's flexible and consultative approach was appreciated, especially its willingness to consider context-specific adaptations through risk-based interpretations. This flexibility helped sustain institutional engagement and fostered trust in the process.

At the same time, the broader sustainability of the certification program depends on continued capacity building and domestic ownership. While 45 assessors and 83 implementers were trained, many Member States lack structured mechanisms for redeploying these experts or embedding certification into national regulatory frameworks.

In countries where certification assessments were conducted, stakeholders noted that formal systems for post-assessment follow-up, periodic recertification, and institutional learning had not yet been established. Respondents emphasized the importance of developing structured mentorship and refresher mechanisms to ensure assessors and facilities remain aligned with evolving standards. Limited domestic funding for BSBS remains a persistent constraint. The lack of sustainable financing — both for institutional infrastructure upgrades and national certification management — threatens to stall progress made under the BSBS Strategic Plan.

*Majority of the African countries unfortunately are still donor dependent... biosafety should be institutionalized and part of the health budget."

Stakeholders emphasized that for certification to be sustainable, it must be fully institutionalized within national health systems, with policy-level integration, budget allocations, and formal recognition of trained personnel and certified facilities. Embedding certification into existing national quality assurance, laboratory regulation, or biosafety frameworks was seen as a critical next step.



Case Study 1: Certification of UVRI (Uganda Virus Research Institute)

UVRI in Uganda was the first laboratory in Africa to be assessed and certified under the Africa CDC's regional biosafety and biosecurity framework. The certification process was initiated through a government-led application submitted to Africa CDC via the Ministry of Health. Africa CDC deployed a team of assessors that ranged from 5-6 depending on size and scope of the assessed facilities who conducted an in-depth review using the regional checklist.

*"With a checklist from Africa CDC... we met the standard — I think almost 100%, well beyond the pass mark."



Figure 16: Assessment team and staff from the UVRI

The process involved practical assessments, SOP reviews, identification of non-conformities (NCEs), and follow-up submissions of required evidence, photos, and documentation.

"They went through the checklist with us, SOPs, practically looking at things... then brought a report, photographs... and told us we had acquired the marks to be certified."

The Africa CDC checklist also helped UVRI leverage its achievements to pursue international accreditation:

* "We actually attained the ISO 17025 accreditation through SANAS... the biosafety checklist was a big stepping stone."

Despite successful completion of the technical steps, certificate delivery was delayed due to administrative issues, but recognition eventually followed:

* "We should have had the certificate by September 2024... we got it in late April... but now we finally have it."

Despite delays in certificate delivery, outcomes included improvements in training, SOPs, waste management, and compliance culture:

* "We had to show training reports on fire, waste disposal, incineration, first aid... these added something to general operations."

UVRI's journey demonstrates the strategic value of national ownership, inter-agency cooperation, and the catalytic role of regional tools in achieving both regional and international recognition.

"They went through the checklist with us, SOPs, practically looking at things... then brought a report, photographs... and told us we had acquired the marks to be certified."

Case Study 2: Certification Process at Noguchi Memorial Institute for Medical Research (Ghana)

Noguchi was among the first laboratories in Africa to receive certification under the Africa CDC's regional biosafety and biosecurity assessment framework. Prior to the process, the institution lacked a single, harmonized set of standards.

"I did not have any standard or framework or any regulations that I was going with... When I got the Africa CDC one, they came as a complete package."

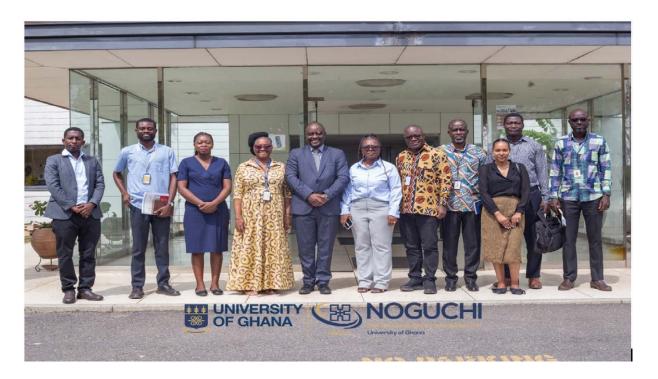


Figure 17: Assessment team and staff from the Noguchi Memorial Institute

The certification process began with an application that included audits, lab layout, and documentation. Africa CDC responded promptly and scheduled an assessment mission. The assessors conducted a two-day site visit, including start-up meetings, documentation review, and a physical walk-through. The lab team received a preliminary report the same evening and convened early the next day to respond to findings.

The assessment process was described as rapid, consultative, and empowering:

*"We met early in the morning and looked at the reports, agreed to most of them... The final report came the next day, and we were promised our certificate in a month."

After an initial rating of 3 stars, the lab provided clarifying evidence and justification for design differences, such as floor materials adapted to seismic risk. Following reassessment, the lab was upgraded to 4-star status.

"We raised some areas where we had evidence... Those changes got us to a 4-star facility." The process improved both documentation systems and confidence in compliance. It also demonstrated how certification can accommodate local realities while maintaining standards.

*Currently, we are doing additional risk assessments. The assessors advised us on how to document effectiveness."

Noguchi's experience shows that with institutional commitment and external support, certification can drive meaningful biosafety upgrades and international recognition.

Several assessors raised concerns about the limited time allocated for institutional assessments, especially when evaluating biocontainment facilities. The current practice of scheduling two-day assessments was considered insufficient for both conducting the technical review and compiling a quality report — particularly when complex infrastructure elements such as access control, ventilation systems, and biosafety cabinet performance are involved.

"I think time is not enough for assessment. They normally allocate you only two days. Two days for me is not enough for an assessor to work and prepare a report. Maybe increase number of days to four, especially when we are assessing biocontainment."

This challenge highlights a systemic issue in the rollout of certification activities: compressed timelines may compromise the thoroughness and credibility of assessments, particularly in facilities where documentation is incomplete or where infrastructure must be verified against minimum standards. The gap in infrastructure readiness led to delays in certification, despite strong technical preparation. It underscores the need for a more integrated approach, combining training and assessment with targeted investments in infrastructure improvement—especially for facilities handling high-consequence pathogens.

"The country does not yet have a fully functional and certified high-level biosafety laboratory, which significantly limits its capacity to diagnose or conduct research on high-consequence biological agents," mentioned a survey respondent.

Case Example: National Adaptation of Certification Framework in Ethiopia

A survey respondent from Ethiopia reported that the country had successfully customized the regional high containment certification checklist to suit its BSL-2 laboratory context, demonstrating how countries can locally adapt regional tools for broader implementation. The adapted framework was implemented as a national certification program, resulting in the certification of 16 BSL-2 laboratories across the country.

This example highlights the practical applicability and scalability of the Africa CDC certification model when appropriately contextualized. It reinforces the importance of developing an adaptation guide for BSL-2 and Level II facilities as part of the next strategy to enable more countries to replicate Ethiopia's success.

Priority Area 4 Summary

Table 14: Summary of Achievements and Opportunities for Improvement and Strategic Implications for Priority Area 4

Summary of Achievements	Opportunities for Improvement and Strategic Implications
✓Certification model and minimum standards checklist developed and rolled out	Develop and disseminate an adaptation guide to solve the contextual limitations in meeting minimum certification criteria by countries
√3 institutions certified; 1 additional laboratory assessed	Address delays in certificate delivery (e.g., UVRI) and establish digital certificate tracking and follow-up systems
✓ 45 assessors trained across 21 Member States	Scale up training for assessors and implementors; address retention through ongoing engagement, incentives, and mentorship
√83 implementors trained across 35 Member States	☑Institutionalize certification tools within national regulatory systems to promote sustainability and standardization
✓ Institutions reported using certification tools for internal biosafety audits	Improve awareness and uptake at facility level through targeted engagement, especially in underperforming regions
✓ 87% of surveyed institutions found the checklist practical and relevant	Involve Regional Technical Working Groups (TWGs) in follow-up assessments, mentorship, and regional learning exchanges
	Reduce reliance on donor funding by advocating for domestic financing lines dedicated to biosafety certification programs
	Advocate at policy level for institutionalisation & integration into national systems through adaptation of certification checklists & minimum standards into national biosafety and biosecurity regulations
	Provide support for infrastructure improvement and re-certification pathways to ensure long-term compliance and sustainability

Key Challenges

- Infrastructure limitations in facilities delayed certification readiness
- Contextual limitations in meeting technical criteria
- Inconsistent national follow-up and support after certification
- Certification delivery delays for example Uganda Virus Research Institute (UVRI)
- Donor dependency limited national ownership and sustainability
- · Retention of assessors was weak following initial training cycles
- Lack of policy-level advocacy for mainstreaming certification frameworks
- Absence of digital systems to track certification status and follow-up



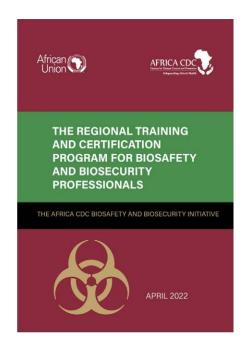
8.2.5 Priority Area 5: Establishment of a regional training and certification program for biosafety and biosecurity experts

Based on the expressed and observed needs to be implemented through the BBI, Africa CDC developed the 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 BSBS as a profession. Key partners include the International Federation of Biosafety Associations (IFBA), African Federation of Biosafety Associations (AfBSA), national BSBS associations and institutions of higher learning.

Africa CDC proposed implementation of the regional training program through at least three (3) Regional Centers of Excellence (COE) and planned to 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.



REGIONAL TRAINING AND CERTIFICATION PROGRAM FOR BIOSAFETY AND BIOSECURITY EXPERTS

- Biorisk Management
- Certification of BSCs
- Certification of Institutions Handling HCAT Biocontainment
- Biological Waste Management

Regional Centres of Excellence, Universities, IFBA, AfBA, ASLM academy

Recognizing biosafety and biosecurity as a profession

Competency Based Learning model for BSBS Certification

Level 3:

Expert level field and practical experience

Level 2:

Hands-on and field competency evaluations

Level 1:

Didactic raining at RCoEBB

Safeguarding Africa's Health

Figure 18: Implementation Framework of the Regional Training and Certification Program for BSBS Professionals

Effectiveness

To address widespread BSBS capacity gaps across the continent, Africa CDC developed and rolled out a regional training and certification program as a flagship intervention under the BSBS Strategy. The program was co-developed with Member States to ensure continental ownership, technical relevance, and alignment with Africa's workforce development needs.

*"Africa CDC came in with this strategy plan to really structure something that was needed in Africa... to ensure that African experts are recognized and listed in the Africa CDC list of experts."

Three of the five regions implemented the program through a designated Regional Centre of Excellence (RCoE), using Africa CDC's tiered certification pathway. This pathway spans three progressive levels (Levels 1 to 3) and four specialization tracks, providing a structured learning and certification process for professionals in biosafety, biosecurity, and biorisk management.

*"We implemented this through Regional Centers of Excellence, so each region is supposed to have its own center that caters for the countries in that region."

According to Africa CDC's intervention logic, the program achieved the following by 2025:

- 315 participants completed Level 1 certification
- 45 participants began Level 2 training
- More than 50 Subject Matter Experts (SMEs) were trained across all five regions

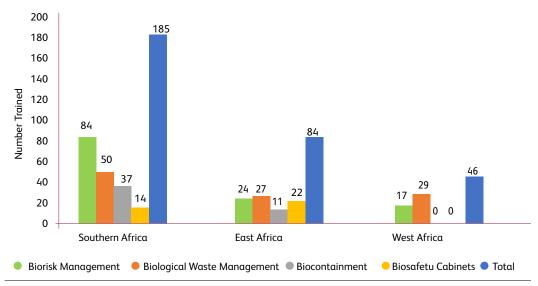


Figure 19: Summary of Professionals certified under the regional training program

Level 1 served as the entry point for practitioners seeking foundational knowledge, while Level-2 training expands on Level-1 by emphasizing the practical application of enhanced procedures for handling moderate-risk biological agents. This tiered approach incentivized participants to continue advancing and institutionalize the knowledge gained within their workplaces.

Survey results confirmed that the program reached a broad audience: 59% of respondents (n=147) reported having received BSBS training under the 2021-2025 strategy. Among those who rated its relevance, 94% (n=86) found the training to be very or mostly relevant. A majority (61%, n=54) also reported that their institutions fully supported the application of the knowledge and skills gained in practice to a great extent.

Feedback from trainees and trainers indicated that the curriculum was relevant, the delivery effective, and the tiered structure motivating.

*"The regional training and certification program — it's life changing. Once you go through those different trainings... it's so easy to come back to the lab and implement biorisk."

A former trainee described the cascading impact of training in their institution and country:

*"With the training, I was able to convince my institution to fund others for certification. Some trainees have now become national and regional trainers. For me, that is effectiveness — the program created trainers who are now scaling it nationally."

Some respondents also referenced internal post-training evaluations conducted at Level 2, using participant self-assessment tools to gauge competency improvement and confidence.

And I have measured the effectiveness through the standard tool — that measures how people feel or what they think about the training and the skills they have acquired. So, with the report I'll be submitting for my Level 2, I think we are going to find a good indicator of how effective the trainings have been. Moving from Level 0 to Level 2, we can say the training has been effective. Because I've been trained on biorisk management, I've been able to convince management to fund others for the certification program. So, we can see that it is through the training at NICD that we now have trainings being scaled down to others nationally. Some of those trained are now trainers in the subject and have participated in regional trainings. For me, that is effectiveness in terms of the certification program."

Despite strong anecdotal evidence, an official from the Examination and Certification Committee (ECC) acknowledged that a formal impact assessment of training effectiveness had not yet been conducted:

*Effectiveness can only be assessed if you go to where they are and check whether it's effective. Right now, there is no evidence. We know we have trained people, but whether they have improved, we cannot tell." – ECC Member

The ECC is tasked with ensuring standardization, alignment with international standards and ensuring visibility and wider recognition of the training and certification program

Still, the RCoE model was widely seen as a credible and regionally owned mechanism for capacity building. It ensured standardized content delivery while allowing localized adaptation to regional needs. Across all five regions, stakeholders credited RCoEs with improving access to technical expertise and fostering a growing cadre of certified biosafety and biosecurity professionals.

Implementation

The implementation of the Africa CDC-led training and certification program was widely praised for its structured design, practical orientation, and alignment with institutional needs across diverse BSBS settings. Respondents across regions emphasized that the model supported real-world application of skills and fostered a learning culture grounded in mentorship and hands-on training.

Implementation was spearheaded by Regional Centres of Excellence (RCoEs), which were competitively selected under the guidance of Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs). By the end of the strategy period, three of the five RCoEs (60%) — in Southern, Eastern, and Western Africa — were fully operational.



Figure 20: The three Regional Centres of Excellence operationalized during the strategy period

These centers became key delivery hubs for Level 1 and Level 2 training, mentorship programs, and assessor development initiatives.

*"They're doing training and setting up a pool of SMEs — that's now being used across Member States."

The training rollout followed a tiered structure aligned with Africa CDC's certification framework. It included foundational training (Level 1), intermediate applied skills (Level 2), and a pipeline for developing Subject Matter Experts (SMEs). The tiered design enabled step-wise progression, encouraging learners to advance professionally while enabling institutions to cascade knowledge internally.

★"I am currently providing mentorship for one of the Level 2 candidates... it has far-reaching implications for veterinary labs within the Tanzanian ecosystem."

The program's design encouraged local ownership. Trainees applied lessons directly within their institutional contexts, and many served as in-house trainers or mentors, contributing to a multiplying effect at national and regional levels.

*"In our lab, we've implemented some of the teachings — refining our biological waste management plan and doing proper risk assessments. Management now takes these seriously."

Beyond institutional uptake, the training model also supported system-wide integration. Several countries began developing or adapting local curricula for universities or national programs using content from the BSBS training modules.

*We now have a Bachelor of Science in Biosecurity at one of the universities in Kenya, developed using content from the national curriculum."

The RCoEs not only facilitated training delivery but also served as platforms for cascading knowledge through step-down trainings, workshops, and recruitment of regional assessors and trainers. This decentralized approach allowed for greater flexibility and responsiveness in training rollouts. However, implementation challenges were reported. Not all regions had operational RCoEs during the strategy period, which created disparities in access. Some Member States, particularly in Central and North Africa, reported delays in engaging with RCoEs or uncertainty about hosting arrangements.

"In our region, it was straightforward to enroll and access training through the RCoE. But colleagues from other regions mentioned they had to wait longer or weren't sure when theirs would become fully operational."

Despite some limitations, the implementation process helped embed a culture of professionalism and catalyzed new career pathways in biosafety and biosecurity. Respondents viewed the certification structure as more than a training exercise — it inspired ambitions for academic advancement and professional identity.

Overall, the implementation of the training and certification program demonstrated the feasibility of regionally coordinated, context-specific capacity building in biosafety and biosecurity, while laying the foundation for long-term professional development systems across Africa.

Impact

The Africa CDC training and certification program under the BSBS Strategic Plan led to tangible changes at the individual, institutional, and national levels. Its impact extended far beyond attendance figures, resulting in cascading trainings, institutional reforms, and strengthened biosafety systems across the continent.

Survey Findings

Survey results demonstrated that the program meaningfully influenced both knowledge acquisition and practical application:

- 36% (n=85) of respondents reported improved knowledge and skills from BSBS training
- 21% (n=86) reported extensive application of the knowledge gained
- 86% (n=86) reported that the training improved institutional practices
- 62% (n=86) said their institution provided tools, resources, or follow-up support after the training
- 11% (n=54) were fully supported by their institution to apply BSBS knowledge and skills gained

These findings confirm that the program not only improved awareness but also catalyzed action and implementation.

The training program resulted in measurable changes at individual, institutional, national and regional levels.

Individual-Level Impact

Many trainees became trainers, mentors, or champions of biosafety initiatives in their institutions or countries. Their activities included lab audits, student mentorship, drafting of policies and SOPs, and national-level engagement.

*"I started weekly training of student interns on biosafety and biosecurity as well as ongoing risk assessment."

Others used their training to launch institution-wide or sectoral reforms:

*"Currently working on the In-Country Improvement Project on Biological Waste Management which is involving all veterinary laboratories within the institution's jurisdiction."

*I have applied my skills in implementing biosafety in a bacteriology testing lab and assessing biosafety practices in laboratories within the One Health lab network."

Institutional-Level Impact

Respondents reported that many institutions revised SOPs, upgraded containment procedures, or introduced new biosafety governance structures:

*"We developed SOPs, guidelines, and tools. We now have certified biosafety experts in the country who are also training others."

*Training of personnel in BSBS at the national level and at the Pasteur Institute. I train new recruits and the institute's staff... I am co-responsible for the BSL-3 in my institution."

*"We were able to conduct step down training using the skills gained during the Africa CDC training."

National and Regional-Level Impact

The Regional Centres of Excellence (RCoEs) helped build a pipeline of biosafety professionals who went on to shape training, policy, and implementation efforts in their countries. Several alumni led institutional reforms, launched national programs, or mentored others through Level 2 certification.

* "After training through the RCoE, we revised our internal BRM strategy and developed new SOPs for the lab."

*"We have a national TWG, and now every province has a provincial BSBS TWG led by trained biomedical scientists — most were trained under Africa CDC."

 \mathscr{S} "Now that I've gone through it, I'm mentoring someone from Level 1 to Level 2 — it's building a whole ecosystem."

The program also promoted long-term professional growth and the emergence of new leaders in biosafety and biosecurity across regions.

Sustainability

The Africa CDC training and certification program laid a solid foundation for sustainability through its structured curriculum, mentorship model, and development of regional training capacity. However, stakeholders raised several concerns that may limit the long-term impact of the initiative if not addressed in the next strategic phase.

Key Challenges to Sustainability

Despite its reach and relevance, the program faced persistent challenges across multiple domains:

- Language barriers and limited regional equity restricted access in some regions, particularly where materials or trainers were not available in Africa's official languages.
- Post-training follow-up was inconsistent, especially for Level 1 trainees, many of whom lacked mentorship opportunities or clear pathways to progress.
- The absence of formal integration into national human resource systems meant that certified professionals were not always recognized or rewarded within institutional career structures.

Delayed implementation of two areas of specialization (Management of High Containment facilities and Installation, Certification and Maintenance of Biological Safety Cabinets), competencies that are critically short in the Africa Region. The delayed start was attributed to late initiation of the curriculum development and approval process.

*"We trained people — but whether they improved, we cannot tell unless we evaluate them where they work."

ᢞ "We need support for advanced levels and mentorship… It shouldn't end at Level 1."

*"Those people that were trained on biosafety and biosecurity should be recognized regionally so that they can be taken seriously when they uphold matters to do with biosafety and biosecurity."

While many trainees went on to implement step-down trainings, revise SOPs, or mentor others, the sustainability of these outcomes depends on whether countries embed the training into their national policies, certification systems, and health workforce development plans.

Role of RCoEs and Regional Support Systems

The RCoEs are widely seen as a strategic asset of the BSBS strategy, providing a continent-wide platform for delivering standardized, yet adaptable training.

However, several stakeholders expressed concern that the full potential of the RCoEs may not be realized without:

- Long-term financing to support recurring training cycles
- Wider regional coverage, especially in underserved areas
- Formal institutional linkages with national HR and public health training systems

*"We should not stop at Level 1. RCoEs need to keep going — and countries need to recognize these certifications."

For the training program to become a sustainable and scalable model, its certifications must be recognized by national institutions, supported through predictable funding, and institutionalized within HR systems (e.g., job descriptions, professional requirements, career pathways).

Priority Area 5 Summary

Table 15: Summary of Achievements and Opportunities for Improvement and Strategic Implications for Priority Area 5

Summary of Achievements	Opportunities for Improvement and Strategic Implications
✓ Regional training and certification program established and operationalized	Advocate for national-level recognition and integration and involvement of mentors and certified personnel into public health systems
√315 trainees completed Level 1 certification	Introduce structured post-certification deployment and career advancement pathways for certified individuals
✓45 participants began Level 2 certification	Standardize multilingual training materials and recruit trainers proficient in Africa's official languages
✓ More than 50 African Region Subject Matter Experts were trained across all regions	☑ Institutionalize mentorship and post-training tracking systems to ensure continued engagement and skill application
✓ Step-down trainings and curricula developed in multiple countries	Establish incentive and recognition mechanisms for mentors and certified personnel
✓ Positive feedback on real- world application (strategy development, audits, SOPs)	Strengthen country ownership and advocate for domestic funding of biosafety training programs
	Align ECC & RCoEs with international certification standards to boost credibility and cross-border recognition
	Develop a formal Monitoring & Evaluation framework for RCoE and national training impact assessment

Summary of Achievements	Opportunities for Improvement and Strategic Implications
	Integrate gender equity considerations and promote gender balance in training participation, mentoring, and certification efforts
	Expand RCoE coverage to all regions with equitable access and facilitate the formation of a regional BSBS Training Advisory Group (TAG)
	Endorse inclusion of BSBS content in undergraduate curricula across MS
	Conduct a deeper analysis of the financial sustainability model for RCoEs to ensure long-term program continuity and reduced dependency on external funding
	Strengthen the network of RCoEs to promote collaboration, regional expertise exchange, and harmonization of BSBS training standards across MS
	Institutionalize RCoEs training outcomes in national career pathways, HR systems, and public sector job descriptions

Key Challenges

- Post-training follow-up has been inconsistent across regions
- Training delivery did not fully align with Africa's official language diversity some materials and trainers were not accessible to Francophone, Lusophone, or Arabicspeaking participants



- Certified personnel and mentors are not formally integrated into national HR structures in most Member States, limiting institutional uptake
- Lack of National-level integration & involvement of Mentors & Certified personnel
- Limited incentives or recognition mechanisms for mentors and certified professionals
- · Country ownership and domestic funding remain weak, increasing dependency on donor support
- ECC and RCoEs are not yet certified or endorsed at the international level, affecting institutional legitimacy
- Lack of a structured post-certification deployment system hinders practical workforce utilization
- Limited Monitoring & Evaluation framework for tracking long-term impact of training programs
- No explicit gender equity strategy in training selection, delivery, or mentorship structures

8.2.6 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 the initiative, Africa CDC proposed to identify and strengthen BSBS aspects of NPHI and NRL to complement other capacity-building needs for surveillance, diagnostics and response. The support to the NPHIs and NRLs was to build capacity on

BSBS including integration of the BSBS principles in day-to-day operation and infrastructure development.

A survey on the BSBS capacity needs for those facilities was conducted following which infrastructures upgrading support and a training and capacity building program was developed, reviewed, and endorsed by AU MS through the RBB-TWG and implemented. Training was conducted in collaboration with the established RCoEs. Thereafter, a rapid assessment report for NPHI and NRL biosafety and biosecurity gaps was produced.

The support was expected to include (i) infrastructural improvements to meet the agreed minimum standards for BSBS (ii) BSBS 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 BSBS.

As part of monitoring high-risk pathogens, Africa CDC established 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.

Effectiveness

In order to enhance BSBS capacities across the continent, Africa CDC, in collaboration with key implementing partners, coordinated targeted training and capacity-building initiatives. One of the major achievements was the development of a standardized six-day Training of Trainers (ToT) program in BSBS. As a foundational indicator, a training, capacity building and certification program addressing biosafety and biosecurity gaps for NPHI and NRL was developed by 2021. Initially tailored to the COVID-19 context, the program was adapted for broader pandemic preparedness. The program was designed to build sustainable local expertise by equipping trainers with the knowledge and skills needed to educate frontline health and laboratory professionals in their respective countries.

The training programs were successfully implemented in 12 AU Member States, covering multiple regions including East Africa (Kenya, Uganda, South Sudan), Southern Africa (Eswatini, Zimbabwe, Zambia), West Africa (Liberia, Niger, Togo) and Central Africa (Cameroon, Democratic Republic of Congo, and Republic of Congo). These efforts ensured alignment with Africa CDC's broader continental strategy for a harmonized and effective pandemic response.

The BSBS Strategy contributed to tangible improvements in BSBS capacities across several Member States, particularly within National Public Health Institutes (NPHIs) and National Reference Laboratories (NRLs). Institutions reported improved planning, internal documentation, and staff practices. Survey findings confirm that the training had lasting impact. Several institutions reported the development of SOPs, manuals, and reference documents as a direct outcome:

*"Development of reference documents: biosafety and biosecurity manuals, standard operating procedures (SOPs), guides for transporting biological samples and risk assessment tools have been developed for biomedical laboratories."

The trainings did not just occur in isolation — they contributed to practical institutional changes, such as SOP adoption, routine biosafety reviews, and improved operational practices. Africa CDC's role in developing regionally aligned SOPs, and guiding national biosafety strategies, was widely acknowledged.

Others highlighted how the training cascaded to local institutions and improved outbreak detection:

"Another component was to capacitate the public health laboratories to detect emerging diseases. As we are speaking right now, within the country, we have the capacity to detect the outbreak for prompt response. We have experienced two outbreaks so far of Marburg, and we managed to detect them within the function. All those are remarkable improvements that came through this strategy plan."

And those countries that were trained — if you go to those countries, you will find that many institutions now have their biosafety and biosecurity guideline or manuals, there are procedures they are using. Before this strategy started, some countries didn't even have a biosafety manual. Now they have SOPs, guidelines, and have set up training programs for staff."

Although BSBS principles were increasingly reflected in day-to-day institutional practice — from structured planning to the enforcement of SOPs and policy instruments, implementation was not uniform across all Member States. While some institutions institutionalized training outcomes, others remained dependent on external support. As one official observed:

*"The national reference laboratory needs to extend the training to the countries which have not yet received it. And also follow up to cascade this training. And finally, also to upgrade infrastructures."

While the initiative succeeded in laying a foundation for more resilient BSBS systems in NPHIs and NRLs, sustained improvements will depend on ongoing technical support, consistent infrastructure maintenance, and follow-through at national level. These insights suggest that future efforts should focus on helping institutions translate foundational inputs into operational, budgeted, and enforceable systems.

Implementation

The priority area of the Strategic Plan was to improve the capacities of the of the NPHIs and NRLs for them to be able to then detect and quickly respond to event of public health content. The major intervention under this was supporting infrastructural upgrades to facilities to meet international standards for BSBS, however there was no funding to support such capital investments. In addition, participants were trained in biosafety and biosecurity, a training of trainers was done using a curriculum which was developed and that was implemented in 12 countries. Implementation of the priority area varied widely across Member States, often reflecting differences in the maturity of NPHIs and NRLs. Countries with established institutes were better positioned to integrate BSBS principles, while others faced structural barriers. As one official explained:

"A number of countries are at different levels in terms of National Public Health Institutes, which makes it difficult for us to push issues around biosafety and biosecurity because we still have a number of countries that are yet to establish functional NPHIs. That also has a limitation in terms of how the agenda can be pushed."

Survey responses revealed operational challenges:

- Lack of financial resources for equipment, laboratory upgrades, and protective materials.
- Shortage of trained biosafety professionals.
- Logistical hurdles in certifying biosafety cabinets and maintaining infrastructure.

"Most institutions in Africa or most laboratories, they are donor dependent when it comes to equipment, so when it comes to certifying their biological safety cabinets sometimes it's not even within their budgets to even certify the cabinets. So, this poses a risk to the workers because now they're going to be working with biological safety cabinets that are not certified in the lab to be waiting for donor funds."

"We still have inadequate local capacity to produce and prepare the reagents specific for outbreak disease response...and everything to support the detection of emerging infectious diseases, during outbreaks and during routine work. So, we are preparing all these reagents outside the continent, and sometimes it's difficult and we have experienced shortage of reagents especially during COVID when each country was responding and the manufacturers were unable to supply the commodities. So, we would wish we could have the country capacity to produce all these materials locally or regionally."

The implementation record shows that while the training target was achieved, the targets for infrastructure upgrades (10 planned by 2025) and equipment certification (5 planned) were not met due to funding gaps. The major intervention under this priority area was supporting infrastructural upgrades to facilities to meet international standards for BSBS. However, there was no funding to support such capital investments. The plan is to provide more focus on this priority area in the (2026-2030) Strategy period.

"We were supposed to support National Public Health Institutes and National Reference Labs to institute some of these biosafety and biosecurity standards and core principles. But I think because of limitation of resources, we didn't really go very far in terms of institutional capacity building at National Reference Labs and National Public Health Institutes. So, I think that was a challenge, resource was very limited. And many countries requested us to support them. We were not able to reach all of the countries because of the resource limitation. Resource both financial and also human resource from our side."

"We need really to put resources into infrastructure development. We were mostly addressing technical support activities in phase one...you tell laboratory technicians and technologists on biosecurity and so on, but you see some limitations in terms of some resource, for example, the economic mechanism, you know, to certify their biosafety cabinets annually. And they may have some limitations on major personal protective equipment and so on. You know, some infrastructure supporting phase two is necessary so that whatever we said is incorporated in the National Reference Lab or National Public Health Institute."

Impact

Despite uneven implementation, the initiative had significant impact on institutional practices and outbreak response capacities. The impact of these initiatives has been significant, strengthening national BSBS frameworks, improving laboratory safety standards, and enhancing pathogen containment measures. Laboratories reported improvements in biosafety practices, containment, and surveillance. Additionally, the program has empowered local trainers to sustain capacity-building efforts beyond the pandemic, fostering long-term resilience. Moving forward, Africa CDC plans to expand these training programs to additional Member States while integrating lessons learned into future health security strategies to ensure continued preparedness for emerging public health threats. Several stakeholders also described how BSBS activities led to improved preparedness and coordination for outbreak response. They highlighted better coordination, more systematic laboratory oversight, and strengthened staff competencies.

* "From our observation, we really have evidence to say, yes, these are changing states, changing policies, changing management practices. And there is a level of awareness in terms of biosafety and biosecurity within the institutions."

*"We have seen local capacity in transporting samples safely from collection facilities to testing laboratories, and local capacity to detect outbreak samples within Member States. Only a few laboratories are now sending samples abroad — most of them are detected within the Member States."

"We had also an Mpox outbreak in our country, and so the interventions on biosafety and biosecurity were definitely very important to control it. Infrastructure enhancement — isolation rooms, hygiene, better waste management — are really, really important."

Another component was to capacitate the public health laboratories to detect emergence diseases and as we are speaking right now, within the country, we have the capacity to detect the outbreak for prompt response and we have experienced two outbreaks so far of Marburg and we managed to detect them within the function so all those are remarkable improvements that came through this strategy plan."

At the policy level, BSBS principles were increasingly integrated into national monitoring frameworks and regulatory systems. For instance:

"And we have incorporated biosafety and biosecurity in our routine monitoring in terms of laboratories looking at the Medical Laboratory Science Council of Nigeria responsible for regulating medical laboratories in Nigeria. So, our checklist now has a lot to talk about in terms of biosafety and biosecurity."

*"Nigerian police have a desk officer. They have a desk on issues of biosafety and biosecurity.

Some of these things were not there in the past."

Several Member States established biosafety committees, reference documents, and monitoring structures to guide laboratory practices. Survey results confirmed improvements in institutional planning, development of guidelines, and awareness across sectors. The BSBS Strategy helped catalyze the institutionalization and cross-sectoral coordination of BSBS. However, the scale and depth of impact varied, and in several countries, such gains are still at an early stage of operationalization.

Sustainability

The sustainability of BSBS efforts remains a central challenge across AU Member States. While some institutions have integrated BSBS into national strategies, budgets, and governance structures, many still rely heavily on external support, with limited domestic ownership of core functions. As one informant noted:

"Without long-term support or government commitment, we risk losing all the progress we've made."

Sustainability remains the most pressing challenge. While training created a pool of trainers and raised awareness, the lack of infrastructure upgrades and persistent donor dependence pose risks to long-term progress.

*"The major problem is the budget definitely. Biosafety and biosecurity are not institutionalized, there is no line item yet for it, and also human resources. We need infrastructure to be better adapted to respond to biosafety biosecurity, and also our equipment is not adequate."

*"Issues of infrastructure and equipment — that one is a hard nut to crack. The new strategic plan should target to include facility-level support, infrastructure upgrades, and compliance audits."

In a few cases, strong government buy-in has resulted in formal national strategies and allocated budget lines. Some Member States have begun integrating BSBS activities into national workplans, budgets and organograms, though dedicated budget lines remain rare.

*You will now find that issues of biosafety and biosecurity are appearing in our national budget. We now have budget lines."

*"In Kenya, biosafety and biosecurity are being institutionalized through undergraduate programs. This builds a pipeline of professionals."

Various stakeholders mentioned that issues around capacity building has to be strengthened in order to ensure that we have the correct human resources that can implement some of the key programs necessary to be implemented. Overall, the initiative succeeded in laying a foundation for institutionalization, but its long-term sustainability will depend on securing national budget allocations, scaling infrastructure investment, and building local capacity for equipment maintenance and reagent production.

"Incorporating biosafety and biosecurity into their pandemic preparedness plans would be another indicator of how this is hopefully sustained at a country level...I think that is a big indicator of the intent to sustain some of these capacities."

Advocacy efforts under the strategy also helped elevate BSBS to higher policy levels and increase visibility across sectors. Respondents also pointed to how strategic advocacy improved recognition and influence:

*We managed to be part of the coordination team and task force under the Vice President's office — something that was not possible before. Now the ministry understands that we need a biosafety and biosecurity authority."

Despite these advances, key institutional gaps persist. Several respondents noted the absence of national-level infrastructure to manage biosafety risks:

*"Most of our institutions, especially those working with pathogens, keep their own records...

There's no centralized national system. That makes accountability difficult."

The issue of long-term financing also emerged repeatedly. While some progress was made in securing national budget lines, donor dependence remains the norm:

*Majority of the African countries unfortunately are still donor dependent... biosafety should be institutionalized and part of the health budget."

Sustainability also hinges on building and retaining a skilled workforce. Respondents emphasized the importance of integrating BSBS into professional development pathways and higher education:

*"We need to have a progression path for biosafety and biosecurity as a profession, like bachelor's and master's degrees standardized across the continent."

*"Kenya launched an undergraduate program in biosafety and biosecurity... If that program is already succeeding, can we try and replicate it in other African countries? That will help build a critical mass of professionals in life sciences."

Lastly, maintaining biosafety infrastructure remains a concern for many institutions — not because new infrastructure was widely delivered during the strategy period, but because essential upgrades and certification support were planned but not implemented. During assessments, infrastructure limitations were noted, though equipment upgrades were not implemented as planned under the strategy.

These reflections suggest that while a foundation for sustainability has been laid, its success will depend on: institutionalizing BSBS into government systems, scaling national ownership, ensuring ongoing coordination and technical support from Africa CDC and expanding access to education and long-term workforce development.

Priority Area 6 Summary

Table 16: Summary of Achievements and Opportunities for Improvement and Strategic Implications for Priority Area 6

Summary of Achievements	Opportunities for Improvement and Strategic Implications
✓ Standardized six-day Training of Trainers curriculum developed	Expand training to additional countries and ensure cascading at institutional level
✓ Training of Trainers in general BSBS in 12 AU Member States; Kenya, Uganda, South Sudan, Eswatini, Zimbabwe, Zambia, Liberia, Niger, Togo, Cameroon, Democratic Republic of Congo, and Republic of Congo. (20 trained per country)	Strengthen NPHIs and NRLs as anchors for national BSBS programs
✓ Trained staff contributed to outbreak detection and safer laboratory practices	Institutionalize BSBS into national budgets, organograms and workforce development pathways
✓ Development of BSBS SOPs, manuals, guidelines and reference documents in trained countries	☑Invest in infrastructure upgrades, equipment certification, local reagent production
✓ Improved outbreak detection capacity (e.g., Marburg, mpox) Strengthened sample transport and laboratory safety practices	Embed BSBS into health security strategies and link implementation to IHR/JEE compliance and sustainability frameworks Build national or regional capacity for local reagent production
✓ Strengthened sample transport and laboratory safety practices	Build national or regional capacity for local reagent production

Key Challenges

- Lack of funding for infrastructure upgrades and equipment maintenance
- Uneven institutional maturity and capacity across Member States
- Donor dependence for equipment certification and reagents
- Shortage of qualified biosafety professionals and limited follow-up on training
- Limited sustainability mechanisms for long-term capacity retention.



Cross-Cutting Challenges toDelivery

The end-term evaluation of the BSBS Strategic Plan (2021–2025) surfaced several recurring and cross-cutting implementation barriers. These challenges, identified through evaluation questions and echoed across all six Priority Areas, reflect systemic gaps in governance, coordination, equity, and operational capacity. Implementation challenges are presented here as cross-cutting rather than by Priority Area, in recognition of the fact that barriers such as coordination gaps, legal constraints, and inequities in access were consistently reported across multiple domains. This framing allows for a more strategic synthesis of system-level bottlenecks and ensures clearer alignment with overarching recommendations for the next strategy.

A. Governance and Policy Gaps

1. Limited Political Commitment and Government Ownership

Political leadership and institutional ownership were often cited as foundational weaknesses. In the absence of strong political will, countries struggled to prioritize BSBS implementation. This affected legislative domestication, cross-sectoral coordination, and the allocation of national budgets.

"We need to speak about political will and top down approach, as I said, and then finances will come, we need to convince the political decider or decision makers. And there is, I mean, there is, you need, you need a political will in order to get things done and to harmonize this on all sectors."

2. Insufficient Advocacy and Political Engagement

Limited advocacy efforts and weak engagement with senior government actors contributed to reduced visibility and prioritization of BSBS at the national level. Stakeholders noted that without proactive outreach, many ministries lacked awareness of the strategic relevance of BSBS resulting in passive implementation or institutional disconnect.

 \mathscr{I} "To make a lot of advocacy and sensitization in the ministries, that's the area that I feel... it has not yet reached where it should be." — Africa CDC Official

*"The level of awareness in terms of what needs to be done in biosafety and biosecurity... is still low among policymakers." — Member State Official

3. Legal and Institutional Mandates

Several Member States lacked clear legal mandates or coordinating body to oversee BSBS. Without this legal foundation, national enforcement, accountability, and budget allocation remained fragmented.

*"So, I think that the biggest challenge in my view is ownership. There's no ministry or authority that's driving this, and the legislation is either not in place or not known."

B. Coordination and Capacity Constraints

4. Weak Coordination and Communication

Fragmented communication between Africa CDC, national focal points, and implementing partners led to duplication of efforts and missed opportunities for alignment. In some cases, Member States were unaware of regional training opportunities or ongoing TWG initiatives.

 \checkmark "There are no opportunities for people like to collectively come together, even online."

5. Uneven Institutional Capacity and Readiness

Institutions varied widely in their ability to absorb and implement BSBS activities. Some lacked trained personnel, basic tools, or the infrastructure needed to comply with biosafety protocols.

 \checkmark "The facilities are still what they are — we shall talk and talk."

*There are a number of sample transportations happening during emergency. So, if you don't take care of biosafety and biosecurity, it can be a risk to spread the disease and so on."

6. Limited Monitoring, Evaluation, and Reporting (MER) Systems

Many countries lacked national MER systems to track BSBS implementation progress or link activities to measurable outcomes. This reduced opportunities for visibility and learning which made it difficult to verify institutional improvements.

"I contributed to the guide of biosafety biosecurity risk evaluations and Coaching of various agents and technicians, what else. And I did also risk evaluation, as I said, so, yeah, and implementation of biosecurity and biosafety in laboratories."

Evaluation Insight:

A recurring challenge in measuring effectiveness is the difficulty of linking strategic activities — such as training, TWG engagement, or SOP development — to field-level performance. In this evaluation, triangulation across qualitative insights, institutional reporting, and national-level indicators (e.g., JEE, SPAR) was used to assess contribution. However, the absence of routine MER systems in most countries limited direct attribution. Strengthening MER frameworks at institutional and national levels will be essential in the next strategy cycle.

7. Underfunding and Over-Reliance on External Support

Most countries remained dependent on donor support, with limited domestic resource mobilization and national investment in BSBS implementation. This undermined sustainability and limited the scale-up of strategic activities.

*"Majority of the African countries unfortunately are still donor dependent... biosafety should be institutionalized and part of the health budget."

C. Equity and Inclusion Barriers

8. Language Barriers and Limited Inclusion

Francophone, Lusophone, and Arabic-speaking Member States often faced limited access to training, mentorship, and documentation due to the lack of translation and regional language expertise.

"We do not have regional subject matter experts that speak Portuguese or Arabic, for instance, and this limits coordination...we had a lot of problems trying to assess the Portuguese applicants."

9. Regional Imbalance in Strategy Uptake

Progress varied greatly across regions due to uneven operationalization of Centers of Excellence (RCoEs) and regional TWG engagement.

Progress varied greatly across regions due to a combination of structural, operational, and contextual factors. While the establishment of Regional Centres of Excellence (RCoEs) helped accelerate uptake in some areas, it was not the sole determinant of regional disparities. Other limiting factors included:

- **Country-level readiness:** Some Member States lacked TWGs, legal frameworks, or implementation plans to fully engage with RCoE-led initiatives.
- Language and interpretation barriers: Francophone, Lusophone, and Arabic-speaking countries
 faced delays in access to training and mentorship due to limited translation and language-specific
 facilitation.
- Logistical and access constraints: Visa delays, short-notice communication, and lack of funded travel limited participation for some countries, even when RCoEs were available.
- Variability in political prioritization: Countries with less internal commitment to biosafety and biosecurity were less proactive in linking to regional resources.
- Uneven TWG engagement: In some regions, not all countries participated consistently in TWG
 meetings, and multisectoral representation remained limited.

*"One of the challenges really is the difference in training rollouts across regions. Some have centers of excellence, others don't yet."

*"Southern Africa had more trainings because we had our center early... other regions didn't have that advantage."

These structural and coordination issues contributed to unequal access to resources and created a risk of regional disparity in long-term BSBS uptake.

10. Uneven Participation in TWG Structures

Representation in TWGs was inconsistent across countries. Barriers included unstable internet connections, lack of formal nomination processes, and limited representation from relevant ministries and sectors.

"One of the challenges in our collaboration, in our technical working groups, is that we... need improvement gathering all the country representatives together. And I think... the lack of stable internet... did not help us meet together."

 \mathscr{K} "Sometimes not all countries attend TWG meetings... and not all institutions are represented."

D. Operational and Logistical Constraints

11. Logistical Delays and Access Constraints

Visa delays, short-notice invitations, and administrative bottlenecks limited timely access to Africa CDC training opportunities. Some participants reported missing events entirely due to late communication or logistical hurdles.

*"Africa CDC is late in sending out invites for trainings — by the time you apply for a visa, it's too late."

These implementation challenges must be considered in the design of the next strategy (2025–2030), particularly in relation to equity, language access, planning timelines, and regional support structures.

10 Main Lessons Learned from the Implementation Strategies

This section summarizes the key lessons that emerged from the implementation of the BSBS Strategic Plan (2021–2025). These lessons are drawn from across all six Priority Areas and from reflections offered by stakeholders in response to EQ10, EQ9, and through PA-specific analysis. They are organized around five strategic levers essential to shaping the next phase (2025–2030): governance, systems integration, institutional capacity, sustainability, and coordination.

A. Governance and Ownership

1. Political commitment and institutional ownership determine traction

Sustained progress was more likely in countries where BSBS received political backing and where national institutions led implementation. Where ownership was lacking, legal domestication stalled, funding remained external, and implementation was fragmented.

st "Political will differs significantly across countries... so does top management commitment."

*Issues of biosafety and biosecurity are not yet widely known or publicized... trying to find buy-in from management is a major challenge."

2. Legal mandates and regulatory frameworks are prerequisites for scale

Even where training and guidance were available, implementation faltered in the absence of legal backing. Clear legal mandates and designated institutional leads enabled better coordination, enforcement, and national ownership.

*"So, I think that the biggest challenge in my view is ownership. There's no ministry or authority that's driving this, and the legislation is either not in place or not known."

Implication: Prioritize legal domestication and regulatory clarity in the next strategy to enable enforceable implementation.

B. Systems and Integration

3. Integration with national policies improves sustainability

Progress proved more durable when BSBS was embedded into institutional organograms, national plans, or public health strategies. Where this did not occur, efforts remained donor-driven and short-term.

*"We've included BSBS in our national organogram, and we now have a desk officer for biosafety risk management."

*"In our country, we now have a national strategy and an allocated budget line — that didn't exist before the BSBS initiative."

Implication: Future programming should ensure BSBS is embedded in government frameworks, not parallel to them.

C. Capacity and Continuity

4. Training worked best when followed by mentorship, evaluation, and peer learning

The tiered training model was well received, but post-training engagement was inconsistent. Mentorship, refresher trainings, and institutional monitoring were critical to translating knowledge into practice.

"We trained people — but whether they improved, we cannot tell unless we evaluate them where they work."

*I started weekly training of student interns on biosafety and biosecurity as well as ongoing risk assessment."

Implication: Create a structured learning ecosystem that pairs training with evaluation, mentorship, and communities of practice.

5. Facility-level readiness and local implementation vary widely

While regional guidance was clear, local uptake depended on institutional infrastructure, staffing, and awareness. Some labs lacked the tools to implement BSBS protocols, despite training.

*The facilities are still what they are — we shall talk and talk."

*"There is a gap in understanding how IPC fits within the broader framework of biosafety and biosecurity — this affects integration at facility level."

Implication: Localize implementation models and support tiered readiness levels across Member States.

D. Sustainability and Financing

6. Domestic resource mobilization is essential for long-term ownership

Countries that linked BSBS to national budgets were better positioned to sustain implementation. Where this was absent, activities remained donor-dependent.

*Majority of the African countries unfortunately are still donor dependent... biosafety should be institutionalized and part of the health budget."

Implication: Encourage budget advocacy and public financing for BSBS programs.

E. Equity and Coordination

7. Regional coordination structures work best when resourced and inclusive

TWGs and RCoEs were effective when fully staffed, funded, and inclusive of all language groups.

Where logistical barriers or language gaps persisted, participation lagged.

*"Africa CDC is late in sending out invites for trainings — by the time you apply for a visa, it's too late."

*Getting Arabic, French, Portuguese, and English speakers together was not easy... and made coordination difficult."

Implication: Invest in inclusive coordination platforms and digital tools for multilingual, multi-country participation.

8. Regional and technical collaboration accelerates progress

The strategy benefited from consensus-building through regional TWGs and strategic partnerships with organizations such as WAHO and WHO. These partnerships strengthened guidance on certification, legal frameworks, and technical tools.

Implication: Replicate partnership models and scale regional technical inputs to co-create BSBS solutions.

9. National associations and technical champions can extend reach

In countries where biosafety associations or national champions were engaged, outreach and implementation deepened. These actors bridged gaps between national plans and facility-level practice.

Implication: Leverage biosafety associations and national focal points as implementation multipliers.

Conclusion:

These lessons should inform both the design and delivery of the next BSBS Strategic Plan (2025–2030). Key levers — political commitment, legal reform, policy integration, national ownership, equitable access, sustainable financing, capacity-building continuity, operational follow-through and inclusive coordination — should serve as anchors for future design and implementation.



Conclusions and Recommendations

11.1 Strategic Conclusions

The BSBS Strategy (2021–2025) marked a pivotal moment in advancing BSBS coordination across Africa. Anchored within Africa CDC's mandate and delivered through a regionalized implementation model, the strategy introduced essential tools, frameworks, and a tiered training and certification system. These initiatives significantly increased awareness, visibility, and momentum around BSBS across Member States. Progress was most visible in areas such as the establishment of Regional Technical Working Groups (RBB-TWGs), roll-out of a certification framework for institutions handling High Consequence Agents and Toxins (HCAT), and the development of the AU-endorsed BSBS Legal Framework.

However, despite these milestones, implementation was uneven across Member States and regions, and many improvements remain dependent on donor support or pilot-stage momentum. Deeper structural and systemic bottlenecks—such as fragmented coordination, limited domestic financing, and inconsistent political buy-in—undermined sustained institutional change in several contexts.



Based on the evaluation findings, five strategic conclusions emerge: Africa CDC's role was catalytic, but uneven regional impact reflects capacity constraints.

Africa CDC provided essential continental leadership, but regional effectiveness depended heavily on staffing levels, funding flows, and the strength of coordination mechanisms. Some regions moved faster due to pre-existing institutional relationships or stronger partner presence.

Training and certification initiatives created strong foundations, yet post-training institutionalization remains weak.

The tiered training model and professional certification programs were widely valued. However, limited follow-up mentorship, unclear career pathways, and weak institutional absorption hindered long-term capacity retention in many Member States.

Legal domestication of the AU framework is significantly delayed.

Despite progress at regional level, national adaptation of the AU BSBS legal framework lagged behind. Countries faced challenges ranging from limited legislative capacity to competing legal priorities and political inertia.

Facility-level risk management practices improved in select countries, especially through certification pilots.

Assessment and certification efforts catalyzed tangible improvements in infrastructure, SOP development, and risk assessment tools—but these gains remain localized and insufficiently scaled.

Sustainability is the most pressing unresolved issue.

In the absence of nationally owned strategies, budgets, and integration into core health and agriculture systems, many gains risk stalling. Underfunding, reliance on donor support, and low political prioritization continue to limit institutional and operational sustainability.

11.2 Strategic Recommendations

A recurring message from stakeholders was the importance of building on the achievements of the 2021–2025 Strategic Plan. Many called for continuity, refinement, and scaling rather than starting over. The next BSBS Strategy (2026-2030) should reinforce successful elements — including technical tools, training programs, coordination structures, and strategic partnerships — and focus on embedding these into national systems.

1. Strengthen Strategy Design, Monitoring, and Coordination

*"Africa CDC should ensure that country-level coordination is done with the Ministries and other One Health stakeholders, and not as a side engagement."

- Develop national implementation plans tailored to each country, aligned with regional priorities.
- Use existing guidance and align with multilateral actors (e.g., WHO, WOAH, FAO, UNEP, World Bank).
- Formalize the engagement of One Health and law enforcement/security sectors through TORs and national steering committees.
- Coordinate annual review meetings with Member States and TWGs to track delivery.
- Incorporate SPAR, JEE, GHSI, and sector-specific tools (e.g., PVS) to monitor strategy outcomes.
- Establish a continental M&E dashboard to track BSBS competencies, facility certifications, and legal progress.
- Ensure TWGs include formal representation from national biosafety and biosecurity associations to strengthen technical continuity, promote country-level ownership, and institutionalize coordination beyond individual appointments.
- Ensure TWGs include representation from Ministries of Foreign Affairs to support alignment with international legal instruments, enhance diplomatic engagement, and facilitate multisectoral coordination.

2. Accelerate Legal Domestication and Alignment



"Support countries in developing legal frameworks governing biosafety and biosecurity, based on the AU model."

 ${m x}$ "Assist in the implementation of the strategic plan in Member States, not just in developing it."

- Provide legal mapping, consultation, and drafting support adapted to national legal systems.
- Develop tailored domestication toolkits and offer legislative peer exchanges.
- Align biosafety/biosecurity frameworks with existing One Health, health security, and biotechnology legislation.
- Advocate directly with policymakers and parliamentarians (as done by OPCW).
- Track legal domestication status via a regional reporting mechanism.

3. Enhance Training Continuity and Post-Certification Support



*"Training must be followed by in-country mentorship — otherwise people get trained but nothing changes at their institutions."

lpha "We need to track people post-training, not just train and leave."

- Establish mentorship programs with in-person meetups and peer accountability reports.
- Track trained personnel via TWGs and maintain active rosters for institutional follow-up.
- Integrate BSBS competencies into public sector job descriptions and HR promotion systems.
- Use training impact evaluations to refine curricula and track institutional outcomes.
- Provide e-learning tools and blended models for refresher training.
- Set new training targets based on regional needs and previous distribution patterns.

4. Improve Equity and Accessibility in Implementation



*"We need equal access to TWG and RCoE activities for Francophone, Lusophone, and Arabic-speaking countries."

- Translate tools and training materials into all AU official languages.
- Ensure balanced geographic and linguistic participation across all BSBS platforms.
- Expand participation to veterinary, environmental, academic, and security sectors.
- Increase the pool of multilingual trainers and regional experts.
- Offer youth-focused career pathways through pre-service training (e.g., MMUST), internships, and fellowship programs.
- Strengthen youth engagement by conducting awareness-raising sessions at universities, incorporating BSBS modules into existing degree programs, and promoting pre-service training, internships, and fellowship programs.

5. Institutionalize Sustainability, Infrastructure, and



Government Ownership

*"We managed to get it into the organogram, but that was not possible without external pressure."

- Advocate for BSBS line items in national budgets and inclusion in health sector strategies.
- Institutionalize BSBS roles through public sector job roles and organograms
- Align activities with broader health security and One Health frameworks (e.g., NAPHS, IHR).

- Guide infrastructure investments for HCAT facilities and ensure inclusion in national lab upgrade plans.
- Strengthen procurement and maintenance systems for biosafety cabinets, PPE, and waste treatment tools.
- Leverage existing initiatives such as BIOPREVAIL and WHO Global Laboratory Sustainability programs.

6. Address Emerging Biosafety and Biosecurity Risks from

Technological Advances

 \checkmark "We need guidance on risks from synthetic biology and gene editing — these are coming fast."

- Convene regional consultations on dual-use risks posed by synthetic biology, gene drives, and AI
 in biotechnology.
- Build capacity through workshops and develop regional risk assessment tools.
- Issue Africa CDC guidance on responsible bioscience innovation and oversight mechanisms.

7. Engage the Private Sector and Non-State Actors



*Private labs and universities are often the ones handling dangerous materials, but they're rarely part of the conversation."

- Integrate private laboratories, academic institutions, and NGOs into BSBS training and certification programs.
- Offer incentives for private sector compliance (e.g., eligibility for procurement contracts or recognition schemes).
- Encourage public-private partnerships in infrastructure, equipment maintenance, and workforce development.

These strategy recommendations reflect the lived experiences of implementers, trainers, policymakers, and frontline institutions across Africa. They are both forward-looking and grounded in feasibility. They are intended to inform the development of the next BSBS Strategic Plan (2025–2030) and ensure that the gains achieved to date are sustained and scaled.

12. Annexes

Annex 1: Completed Monitoring and Evaluation Framework

Level	Result Statement	Indicator	Baseline	Target	Status (2025)	Data Source	Key Assumptions
Impact	African Union Member States demonstrate strengthened and sustainable biosafety and biosecurity systems that enable effective compliance with international requirements and regulations such as the International Health Regulations (IHR) (2005) and corresponding Joint External Evaluation (JEE) requirements under the IHR Monitoring and Evaluation framework, the Biological Weapons Convention (BWC) and United Nations Security Council Resolution (UNSCR) 1540 by 2025	Proportion of Member States (MS) with a Joint External Evaluation (JEE) score of at least 3 for both biosafety and biosecurity (P.7.1 and P.7.2) by 2025	3 (5%) 2021	55 (100%)	5 /55 (9%)	WHO JEE Mission Reports	Member States remain committed to undergoing the JEE process
		Proportion of MS that have reported atleast Level 3 achieved for implementation of a laboratory biosafety and biosecurity regime (C.4.2) in the State Party Self-Assessment Annual Report (SPAR) by 2025	16 (29%) 2021	55 (100%)	29 (53%)	State Party Self-Assessment Annual Report	Member States submit timely and complete SPAR reports to WHO
Outcome Strengthen Biosafety and Biosecurity capabilities of the Africa CDC Secretariat, RCCs,	Improved coordination and effectiveness of biosafety and biosecurity interventions through the functioning of Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs)	Percentage of regional biosafety and biosecurity interventions achieving intended results (such as timely implementation, alignment with standards, or improved capacity) with contributions from coordination	0% (2021, TWGs not yet operational)	Not specified	100% – Stakeholder- reported (TWG Chair): "TWGs 100% implemented and succeed."	TWG meeting minutes and action plans, stakeholder feedback	Availability of nominated representatives Relaxation of travel COVID-19 lockdown restrictions

NPHIs, NRLs, and Animal and Plant Health laboratories		by Regional Technical Working Groups (RBB-TWGs)					
	Member States demonstrate progress toward domestication and implementation of the AU Biosafety and Biosecurity (BSBS) Legal Framework	Proportion of Member States with national roadmaps for domestication for the AU BSBS Legal Framework developed by 2025	0%	12	7/12 (58%)	official documentation from MS, progress reports	Political commitment exists at the national level to align with the AU framework
	Improved biosafety and biosecurity capabilities of high-risk pathogen handling facilities in line with established minimum standards	Increase in the percentage of high-risk pathogen handling facilities demonstrating improved biosafety and biosecurity capabilities based on assessment scores aligned to minimum standards by 2025	0% (2021)	Not specified	Outcome not fully measured, Unverified improvement (KIIs)	Facility assessment reports, progress reports	Facilities allow access and participate in assessments
	Enhanced knowledge and skills of biosafety and biosecurity trainees across targeted institutions	Percentage of BSBS trainees who demonstrate improved knowledge and skills in BSBS through pre- and post-training assessments by 2025	0% (2021) No formal pre/post assessment data collected	Not specified	perceived or self- reported evidence	pre- and post- training tests, project staff	Training content is aligned with identified competency gaps
	Improved compliance of high-risk pathogen handling facilities with minimum biosafety and biosecurity standards through targeted infrastructural upgrades	Percentage of high-risk pathogen handling facilities that, following infrastructural upgrades, achieve an 85% or higher compliance score aligned with the agreed minimum biosafety and biosecurity standards-specifically in containment and access control-by 2025	0% (2020)	Not specified	Not done	Facility biosafety and biosecurity assessment reports, progress reports	Upgraded infrastructure will directly improve compliance with containment and access standards
	Strengthened capacity of Africa CDC and RCCs to provide timely and high-quality biosafety and biosecurity technical support to Member States	Percentage increase in Member States receiving timely and high- quality biosafety and biosecurity technical support from Africa CDC and RCCs as a result of functional expert staffing by 2025	0% (2021)	Not specified	Mixed evidence; Some MS satisfied, others noted delays or lack of response. Often tied to staffing levels at CDC/RCCs. Needs validation.	Member States satisfaction survey, program performance reports	Experts are fully onboarded, trained, and retained

Outputs	1. A Biosafety and Biosecurity Legal Framework for the Africa Region	(Foundational) A draft Biosafety and Biosecurity Legal Framework for the Africa Region submitted to the African Union for review and adoption by 2022	(0), 2020	1 draft Legal Framework	100% Fully achieved	Project reports	Existence of a National Public Health Institute in the Member States
		(Foundational) A communication and advocacy strategy for the Biosafety and Biosecurity Framework developed by 2022	0	1	100% Fully achieved	Meeting reports, project reports	Availability of members to participate in meetings
		Number of regional meetings for advocacy and communication engagements for biosafety and biosecurity by 2021	0 (2020)	5	1	Meeting reports, project reports	Availability of members to participate in meetings
		Number of advocacy meetings with identified champions (Ministers of Health, Heads of States, Influential figures) by 2022	0 (2021)	3	100% Fully achieved	Meeting reports, project reports	Availability of members to participate in meetings
		Proportion of MS trained and technical assistance provided on legal mapping, drafting and review of legal instruments by 2025	0%	10 (100%)	8/10 (80%)	Training reports, Progress reports	Availability of members to participate in meetings
		Proportion of Member States with national roadmaps for domestication for the AU BSBS Legal Framework developed by 2025	0%	12 (100%)	7/12 (58%)	Training reports, Progress reports	Availability of members to participate in meetings
		Proportion of MS with domestication plans developed for the Biosafety and Biosecurity Legal Framework by 2025	0% (21)	12 (100%)	2/12 (17%)	meeting report, progress reports	Availability of members to participate in meetings
	2. Five Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWG)	Foundational) Number of Regional Biosafety and Biosecurity Technical Working Group (RBB- TWG) comprising of Africa CDC Secretariat, Member States, the 5 RCCs and Partners established by 2021	0 (2020)	5 RBB-TWGs	5 Fully achieved	Progress report, Meeting notes	Availability of nominated representatives

	Number of quarterly virtual RBB- TWG meetings conducted by 2025	O (2020)	75	100% Fully achieved	Meeting minutes, Activity reports	Availability of nominated
	Number of physical RBB-TWG meetings conducted by 2025	0 (2020)	25	100% Fully Achieved	Meeting minutes, Activity reports	representatives, Relaxation of travel COVID-19 lockdown restrictions
	(Foundational) List of gaps and priority actions required to improve compliance of MS with biosecurity and biosafety requirements based on WHO JEE identified by 2025	0	1	100% Fully αchieved	Report on priority gaps, meeting reports	
3. A Regulatory and Certification framework for institutions handling high consequence agents and toxins	(Foundational) A regional regulatory and certification framework with minimum standards for biosafety and biosecurity for institutions (human, animal, and plant health) handling high consequence agents and toxins, developed, adopted by Member States, and translated by 2021	0 (2020)	1 Framework developed	100% Launched on 8th April, 2022	Consultancy reports, progress reports	Identification of an institution with capacity to develop a certification program
	An assessment tool/checklist for institutions handling high consequence agents and toxins developed by 2021	0 (2020)	1 assessment tool/checklist	1 Fully achieved	Consultancy reports, meeting reports	Identification of an institution with capacity to develop a certification program
	Number of Regional Training of trainers on the minimum standards for high containment facilities by 2023	0 (2021)	3 No specific target, plan to conduct 15 facility assessments for compliance to stan-dards	3	Training report, project reports	Availability of participants

	Number of trainers trained on the minimum standards for high containment facilities by 2023	0 (2021)	No target	83 implementors from 35 MS	Training report, Project reports	Availability of participants
	Number of regional training and certification of assessors by 2023	0 (2021)	No target	2	Training report, Project reports	Availability of participants
	Number of certified assessors trained through the Regional Centres of Excellence (RCoEs) by 2023	0 (2021)	No target	45 Assessors from 21 MS	Training report, Project reports	Availability of participants
	Number of institutions handling high consequence agents and toxins with assessments for compliance to standards conducted by 2025	0 (2021)	15 institutions LABS 3 assessed n certified	3 assessed and certified, 1 assessed and pending certification	Completed assessment reports, Project reports	Availability of facilities to be assessed
	Number of institutions that have received certification to handle high consequence agents and toxins by 2025	0 (No institutions certified under the new regional framework at the start of the strategic plan, 2021)	15 institutions	3 assessed and certified	Activity report, Project reports	Eligible institutions are identified and assessed according to the certification schedule
4. Regional Training and Certification program for Biosafety and Biosecurity Experts	(Foundational) Regional training, capacity building and certification program for Biosafety and Biosecurity professionals including four specialist areas developed by 2021	0 (2020)	1	100% Fully achieved	Finalized training program document, Progress report	Identification of an institution with the capacity to develop a training program
	Number of BS and BS trainings at RCoE by 2025	0 (2021)	72, 2/month	16	Training report, Project reports	Availability of participants
	Number of staff trained in biosafety and biosecurity under the regional program by 2025	0 (2021)	Not specified	315 level 1 Level 2 >50 started >50 SMEs	Training reports, Progress reports	Adequate funding and logistics are available to conduct planned trainings

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	Number of in-country competency assessments conducted to evaluate application of biosafety and biosecurity training by 2025	0	12	Not done	Assessment reports, Project reports	Availability of certifiers and participants
	Number of evaluation and assessment reports for selection of RCoE for Biosafety and Biosecurity by 2025	0	No target	11 (Partially achieved)	Mission reports, Project reports	Availability of countries to host RCoE
	Number of operational RCoEs for Biosafety and Biosecurity by 2025	0	3	3 Fully αchieved	Launch reports, Progress reports	Availability of MS willing and have the capacity to host RCoE
5. Trained and capacitated staff from National Public Health Institutes (NPHI) and National Reference Laboratories (NRL) in areas of prevention, detection and responding to events of public health concern and threats of high consequence pathogens	Rapid biosafety and biosecurity capacity needs assessment for NPHI and NRL including animal and environmental laboratories by 2021	0 (2021)	1 rapid assessment BSBS needs assessment conducted	, BSCs	Assessment report, Progress reports	Member states responding to the survey
	(Foundational) Training, capacity building and certification program addressing biosafety and biosecurity gaps for NPHI and NRL developed by 2021	0	1 Training of Trainers (TOT) curriculum developed	100%	Progress reports	Identification of an institution with capacity to develop program
	Number of infrastructural upgrades/improvements and repairs for facilities handling high risk pathogens to meet the agreed minimum standards for biosafety and biosecurity by 2025	0 (2020)	10	Not done	Infrastructure assessment reports, Progress reports	Availability of facilities to be upgraded
	Number of installations, certification and maintenance of biosafety and biosecurity equipment by 2025	0	5	Not done	Project reports	Availability of facilities to accept the equipment Availability of biosafety equipment

		Number of trainings conducted for staff from NPHI and NRL in areas of addressing biosafety and biosecurity gaps by 2025	0 (2021)	Not specified	12 Implemented in 12 countries	Training reports, Progress reports	Availability of participants
		Bio-surveillance program for identified high consequence agents and toxins (HCAT) by 2025	0 (2021)	1 Bio- surveillance program for HCAT identified	TBD	Progress reports	Availability of regional and national HCAT
	6. Support Human Resources at Africa CDC for Biosafety and Biosecurity	Number of Senior Biosafety and Biosecurity Experts hired by Africa CDC by 2025	1	2	1	HR Records, Progress reports	Availability of BS and BS Experts
		Number of Junior Biosafety and Biosecurity Experts for the RCCs hired by Africa CDC by 2025	1	3	2 Partially achieved	HR Records, Progress reports	Availability of BS and BS Experts
Activities	1.1 Set Up team of Experts and develop Draft 0 and coordinate development and review process of the framework	Progress in identifying and engaging biosafety and biosecurity experts for drafting the regional legal framework by 2020	No experts identified or engaged (2019)	All required experts identified, engaged, and contributed to the drafting process.	TBD	Progress reports, meeting reports	Sufficient number of qualified experts are available
		Status of drafting and translating the regional biosafety and biosecurity legal framework by 2020	No draft or translation initiated (2019)	Draft 0 completed and translated into three AU official languages	100%	Draft framework document, progress reports	Legal and technical experts are available to draft the document
	1.2 Consultative Meetings to review Draft document by Member states, Regional Experts	Status of planning and coordination of regional virtual consultative meetings with Member States and regional experts to review the draft framework by 2021	No meetings planned or coordinated (2019)	5 – All required consultative meetings planned and implemented	1	Meeting reports, progress reports	Availability of nominated representatives

1.3 Advocacy meetings for the BSBS Legal Framework	Status of planning and coordination of regional advocacy meetings with Member States and partners to promote the biosafety and biosecurity legal framework by 2021	No advocacy meetings planned (2019)	5	TBD	Meeting reports, Progress reports	Member States and partners are willing to engage in advocacy discussions
	Coordination of high-level advocacy meetings with identified champions for promoting the biosafety and biosecurity legal framework by 2022	Coordination not initiated (2020)	High-level meetings coordinated and conducted with champions	TBD	Communications and invitation emails, Progress reports	Identified champions are willing and available to participate
2.1 Establishment and operationalization of Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWG)	Status of facilitating the establishment of Regional Biosafety and Biosecurity Technical Working Groups (RBB- TWGs) by 2021	0 – No action initiated (2019)	5 – RBB- TWGs officially launched	100%	Activity reports, Progress reports	Availability of nominated representatives
	Progress in planning and coordinating quarterly virtual RBB-TWG meetings by 2025	0 – No planning initiated (2020)	75 – All planned quarterly virtual RBB-TWG meetings were successfully coordinated and conducted as scheduled	75	Meeting minutes, progress reports	Availability of nominated representatives
	Progress in planning and organizing physical RBB-TWG meetings by 2025	0 – No physical meeting planning initiated (2020)	25 – All planned physical RBB-TWG meetings successfully coordinated and held	25	Meeting minutes, progress reports	Adequate funding and relaxation of travel COVID-19 lockdown restrictions

3.1 Develop a Regulatory and Certification framework for institutions handling High consequence agents and toxins	Status of development of minimum standards and assessment tool for high containment facilities by 2021	0 – No tool or standards exist (2020)	1 standards and assessment tool finalized	100%	Draft and final versions of the tool and standards, progress report	Availability of technical experts
	Status of planning and delivery of regional training and certification sessions for assessors on minimum standards for high containment facilities by 2023	0 -No sessions planned or conducted (2021)	Not specified	5	Training reports, progress reports	Availability of technical expertise
	Status of conducting institutional assessments for certification against minimum biosafety and biosecurity standards by 2025	0 – Not started (2021)	15 – All planned assessments completed	TBD	Assessment mission reports, progress reports	Member States and institutions agree to undergo assessments
4.1 Develop and implement a regional training and certification program for Biosafety and Biosecurity Experts	Status of development of the regional training and certification program for Biosafety and Biosecurity Experts by 2021	0 (No program exists, 2020)	1 regional training and certification program developed	100%	program development reports, progress reports	Identification of an institution with the capacity to develop a training program
	Number of biosafety and biosecurity training sessions conducted under the regional program by 2025	0 (no prior trainings under this specific program)	72 training sessions conducted	16	Training reports, progress reports	Adequate funding and logistical support for training delivery
4.2 Establishment of Centres for Excellence	Number of evaluation missions conducted and reports completed for the selection of Regional Centres of Excellence (RCoEs) for Biosafety and Biosecurity by 2025	0 (No evaluation missions conducted)	5 evaluation mission conducted	100%	Evaluation mission reports, progress reports,	Adequate number of eligible institutions
5.1 Develop a 5 Year regional training and capacity building program	Status of development of regional training and capacity building program for biosafety and biosecurity by 2021	0 (No formal regional training and capacity building program in place	1 Training and capacity building program fully developed, validated, and ready for implementation.	100% Fully achieved	Program document; progress reports	Adequate technical expertise is available to develop the program

	5.2 Implement the 5-year training and capacity building program	Number of high-risk pathogen facilities that underwent infrastructure assessments and received plans for biosafety and biosecurity improvements by 2025	0 (no assessments and planning began with the impleme ntation of the current strategy, 2020)	10 high-risk pathogen facilities	4 Partially achieved	Progress reports, infrastructure assessment reports	Funding for infrastructure projects is timely and sufficient
		Number of biosafety and biosecurity regional training sessions, workshops, or mentorship programs organized for NPHIs and NRLs by Africa CDC by 2025	O (no such training sessions were previously conducted under this regional program).	5 regional training events conducted	12	Training reports, progress reports	Adequate budget and human resources are available to plan and deliver trainings
	6.1 Hiring of Staff for Biosafety and Biosecurity	Number of biosafety and biosecurity staff positions advertised and recruitment processes completed by Africa CDC by 2025	2 staff recruited	5 positions advertised and recruitment processes completed	2 hired	recruitment reports, progress reports	Sufficient resources available to support recruitment efforts
Inputs	Biosafety and Biosecurity Legal Framework	Budget planned	\$106,000	\$736,000	TBD	Financial reports, progress reports	Donor commitments
	Five Regional Biosafety and Biosecurity TWGs	Budget planned	\$0	\$2,180,000	TBD		and government cooperation
	A Regulatory and Certification of High Containment facilities	Budget planned	\$15,000	\$871,000	TBD		
	Regional Training and Certification program	Budget planned	\$319,000	\$4,349,000	TBD		
	Trained and capacity building of NPHI and NRL	Budget planned	\$0	\$8,412,000	TBD		

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Planned inputs

Financial resources for facility upgrades, training, and implementation logistics

Human resources, including Africa CDC staff, technical personnel, consultants, and partner contributions

Technical expertise for regulatory framework development, standard setting, and capacity needs assessments

Biosafety and biosecurity equipment, certification tools, and infrastructure support

Assessment tools, benchmarks, and international biosafety/biosecurity guidelines

Skilled trainers and assessors from Regional Centres of Excellence (COEs)

Training materials and logistical support for delivery and certification activities Institutional support and coordination through the RBB-TWG, COEs, and Member States

Assumptions

No disruption due to natural disasters or outbreaks/pandemics

Financial resources are disbursed on time

Skilled human resources are available and recruited

Annex 2: Full Evaluation Matrix

EQ1 - Overall Strategic Achievement	Q1. To what extent has the BSBS Strategic Plan improved the technical and institutional ca reference laboratories to prevent, detect, and manage biosafety and biosecurity risks?	pacity of Africa CDC, RCC	s, NPHIs, and national
Rationale and Coverage	This question reflects institutional capacity improvements in biosafety and biosecurity at nation	nal levels.	
Evaluation Criteria covered	: Effectiveness, Overall Achievement		
Specific Evaluation Questions	 Did the BSBS Strategy establish a foundation for planning and targeted capacity developmen Were NPHIs and NRLs upgraded with the necessary infrastructure and equipment to meet bio Have NPHIs and NRLs applied strengthened capacity to implement biosafety and biosecurity 	safety and biosecurity sta	ndards?
Judgement criteria and ind	icators	Data sources	
JC.1.1	Planning and capacity development readiness	Primary	Secondary
	(Foundational) Rapid biosafety and biosecurity capacity needs assessment for NPHI and NRL including animal and environmental laboratories by 2021 (Type: Intervention Logic)	KIIs	Assessment report
	(Foundational) Training, capacity building and certification program addressing biosafety and biosecurity gaps for NPHIs and NRLs developed by 2021 (Type: Intervention Logic)	Surveys, KIIs	Progress reports
JC.1.2	Infrastructure and equipment improvements at NPHIs and NRLs		
I-1.2.1	Number of infrastructural upgrades, improvements or repairs completed in NPHIs and NRLs handling high-risk pathogens to meet the agreed minimum standards for biosafety and biosecurity by 2025 (Type: Intervention Logic)	KIIs with NPHI/lab directors	Infrastructure upgrade project reports
I-1.2.2	Number of installations, certification and maintenance of biosafety and biosecurity equipment in NPHIs and NRLs by 2025 (Type: Intervention Logic)	KIIs	Project reports
I-1.2.3	Percentage of NPHIs and NRLs handling high-risk pathogens that, following infrastructural upgrades, achieve an 85% or higher compliance score aligned with the agreed minimum biosafety and biosecurity standards-specifically in containment and access control-by 2025 (Type: Intervention Logic)	KIIs with NPHI/lab directors	Project reports
JC.1.3	Institutional functionality and technical implementation		
I-1.3.1	Bio-surveillance program for identified high consequence agents and toxins (HCAT) by 2025 (Type: Intervention Logic)	KIIs	Progress reports
I-1.3.2	Number of staff trained from NPHI and NRL in areas of addressing biosafety and biosecurity gaps by 2025 (Type: Intervention Logic)	Survey, KIIs	Training reports
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys		

EQ2 - Coordination and Implementation	Q2. To what extent has the BSBS Strategic Plan strengthened the capacity of Africa CDC, RCCs, NPHIs, and national reference laboratories to coordinate and implement biosafety and biosecurity programs?						
Rationale and Coverage	Evaluates whether functional coordination systems were established to implement biosafety/bi	osecurity activities					
Evaluation Criteria covered:	rered: Effectiveness, Implementation						
Specific Evaluation Questions	 Was the staffing at Africa CDC and RCCs sufficient to support BSBS coordination and implementation. Did Member States receive timely and high-quality support from Africa CDC and RCCs? Did RBB-TWGs actively contribute to and support BSBS implementation? 	entation?					
Judgement criteria and indic	cators	Data sources					
JC.2.1	Biosafety and Biosecurity staffing at Africa CDC and RCCs	Primary	Secondary				
I-2.1.1	Number of Senior Biosafety and Biosecurity Experts hired by Africa CDC by 2025 (Type: Intervention Logic)	KIIs	Progress reports				
I-2.1.2	Number of Junior Biosafety and Biosecurity Experts for the RCCs hired by Africa CDC by 2025 (Type: Intervention Logic)	KIIs	Progress reports				
JC.2.2	Timeliness and quality of technical support to Member States						
I-2.2.1	Number of Member States reporting timely receipt of technical support from Africa CDC or RCCs in response to biosafety and biosecurity needs by 2025 (Type: New) RCS in response to biosafety and biosecurity needs by 2025 (Type: New) RCS in response to biosafety and biosecurity needs by 2025 (Type: New)						
I-2.2.2	Percentage increase in Member States receiving timely and high-quality biosafety and biosecurity technical support from Africa CDC and RCCs as a result of functional expert staffing by 2025 (Type: Intervention Logic) KII, Surveys Program perform reports						
JC.2.3	Use and engagement of RBB-TWGs in BSBS implementation						
I-2.3.1	Number of TWG-produced technical outputs (e.g., guidance notes, SOPs, planning templates) cited by RCCs or NPHIs in their implementation activities (Type: New) Meeting reports						
I-2.3.2	Percentage of RBB-TWG members reporting active participation and contribution to BSBS KIIs TWG Meeting minimplementation planning by 2025 (Type: Intervention Logic)						
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys					

EQ3 - Training and Competency Building	Q3. How effective was the regional training and certification program in improving the technical competencies of biosafety and biosecurity personnel, and to what extent have trained individuals applied their skills within their institutions?					
Rationale and Coverage	Evaluates the outcomes of BSBS capacity-building efforts on technical staff performance and practical application.					
Evaluation Criteria covered	: Effectiveness					
Specific Evaluation Questions	 Was the regional training and certification program for BSBS effectively established and imple Did training participants improve in knowledge and apply skills at institutional level? Were RCoEs successfully established and used as regional training hubs? 	mented?				
Judgement criteria and ind	licators	Data sources				
JC.3.1	Design and delivery of regional BSBS training programs	Primary	Secondary			
I-3.1.1	(Foundational) Regional training, capacity building and certification program for Biosafety and Biosecurity professionals including four specialist areas developed by 2021 (Type: Intervention Logic)	KIIs	Final strategy/training framework			
I-3.1.2	Number of BS and BS trainings at RCoE by 2025 (Type: Intervention Logic)	RCoE Training reports				
I-3.1.3	Number of staff trained in biosafety and biosecurity under the regional program by 2025 (Type: Intervention Logic)	KIIs, Surveys	Training reports			
JC.3.2	Training effectiveness and knowledge application					
I-3.2.1	Percentage of BSBS trainees who demonstrate improved knowledge and skills in BSBS through pre- and post-training assessments by 2025 (Type: Intervention Logic)	Pre/post-test results from training participants, IDIs	Competency evaluation forms			
I-3.2.2	Number of in-country competency assessments conducted to evaluate application of biosafety and biosecurity training by 2025 (Type: Intervention Logic) KIIs Follow-up evaluate application of reports					
JC.3.3	Establishment and functionality of RCoEs					
I-3.3.1	Number of evaluation and assessment reports for selection of RCoEs for Biosafety and Biosecurity by 2025 (Type: Intervention Logic) KIIS Mission reports					
I-3.3.2	Number of operational RCoEs for Biosafety and Biosecurity by 2025 (Type: Intervention Logic) KIIs Launch rep update repo					
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys					

EQ4 - Cross-country Collaboration and Alignment	Q4: To what extent has the establishment and functioning of Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) contributed to improved cross-country coordination, knowledge sharing, and strategic alignment?						
Rationale and Coverage	Assesses whether RBB-TWGs are operating as platforms for collaboration and harmonization of	BSBS strategies.					
Evaluation Criteria covered	l: Impact, Effectiveness						
Specific Evaluation Questions	 Were RBB-TWGs established and positioned to support regional coordination? Have RBB-TWGs met regularly and functioned as intended? Did RBB-TWGs contribute meaningfully to the success of regional BSBS interventions? 						
Judgement criteria and inc	licators	Data sources					
JC.4.1	Establishment and structure of RBB-TWGs	Primary	Secondary				
I-4.1.1	(Foundational) Number of Regional Biosafety and Biosecurity Technical Working Group (RBB-TWG) comprising of Africa CDC Secretariat, Member States, the 5 RCCs and Partners established by 2021 (Type: Intervention Logic)	KIIs	Meeting minutes, Activity reports				
I-4.1.2	Percentage of RBB-TWGs with active participation from animal health, environmental, and other One Health sectors by 2025 (Type: New)	KIIs	Meeting minutes, Activity reports				
JC.4.2	Meeting frequency and operational functionality of TWGs						
I-4.2.1	Number of quarterly virtual RBB-TWG meetings conducted by 2025 (Type: Intervention Logic)	KIIs	Meeting minutes, Activity reports				
I-4.2.2	Number of physical RBB-TWG meetings conducted by 2025 (Type: Intervention Logic)	KIIs	Meeting minutes, Activity reports				
JC.4.3	Contribution of TWGs to BSBS implementation						
I-4.3.1	Percentage of regional biosafety and biosecurity interventions achieving intended results (such as timely implementation, alignment with standards, or improved capacity) with contributions from coordination by Regional Technical Working Groups (RBB-TWGs) (Type: Intervention Logic) KIIs Meeting minutes, Active reports						
Data Collection Methods	KIIs, In-depth Interviews, FGDs, Surveys						

EQ5 - Legal Framework Domestication	Q5. To what extent have Member States initiated or developed national roadmaps to dome influenced their uptake?	sticate the AU BSBS	Legal Framework, and what factors			
Rationale and Coverage	Examines progress in domestication of the BSBS Legal Framework and factors influencing implementation.					
Evaluation Criteria: Effectiv	reness, Sustainability					
Specific Evaluation Questions	 Was a legal framework and supporting advocacy strategy developed to enable Member State Were advocacy efforts and technical assistance provided to enable Member States to domesti To what extent have Member States progressed in planning and completing legal domesticati 	cate the BSBS legal fr				
Judgement criteria and ind	icators	Data sources				
JC.5.1	Development of enabling strategy for legal framework rollout	Primary	Secondary			
I-5.1.1	(Foundational) A draft Biosafety and Biosecurity Legal Framework for the Africa Region submitted to the African Union for review and adoption by 2022 (Type: Intervention Logic)	KII	Draft Legal Framework			
I-5.1.2	A communication and advocacy strategy for the Biosafety and Biosecurity Framework developed by 2022 (Type: Intervention Logic)	KIIs	Final strategy document			
JC.5.2	Engagement and support to Member States for domestication	,	,			
I-5.2.1	Number of regional meetings for advocacy and communication engagements for biosafety and biosecurity by 2025 (Type: Intervention Logic)	KIIs	National engagement reports			
I-5.2.2	Number of advocacy meetings with identified champions (Ministers of Health, Heads of States, Influential figures) by 2022 (Type: Intervention Logic)	KIIs	Meeting reports, project reports			
I-5.2.3	Proportion of MS trained and technical assistance provided on legal mapping, drafting and review of legal instruments by 2025 (Type: Intervention Logic)	KIIs	Workshop/training reports			
JC.5.3	Progress in legal domestication by Member States					
I-5.3.1	Proportion of Member States with national roadmaps for domestication for the AU BSBS Legal Framework developed by 2025 (Type: Intervention Logic)	Roadmap documents				
I-5.3.2	Proportion of MS with domestication plans developed for the Biosafety and Biosecurity Legal Framework by 2025 (Type: Intervention Logic)	Draft legislation				
I-5.3.3	Proportion of MS with completed domestication of the Regional Biosafety and Biosecurity Legal Framework by 2025 (Type: Intervention Logic)	KIIs	Enacted legislation, official gazette publications, AU/ MS status reports			
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys					

EQ6 - Risk Management and Compliance	Q6. What evidence exists that institutions handling high-risk pathogens have improved the capacity-building, assessments, and regional standards promoted under the strategy?	ir biosafety and	d biosecurity practices as a result of				
Rationale and Coverage	Evaluates institutional behavior and change post-assessment and training.						
Evaluation Criteria covered	Impact						
Specific Evaluation Questions	 Were the tools and framework for institutional certification developed and made available for Were assessors and trainers adequately prepared to support certification of high-risk institutio Have institutions been assessed, certified, and improved in compliance with biosafety and bio 	ns?	rds?				
Judgement criteria and ind	icators	Data sources	5				
JC.6.1	Development of certification tools and regulatory framework						
I-6.1.1	(Foundational) A regional regulatory and certification framework with minimum standards for biosafety and biosecurity for institutions (human, animal, and plant health) handling high consequence agents and toxins, developed, adopted by Member States, and translated by 2021 (Type: Intervention Logic)	KIIs	Framework documents				
I-6.1.2	An assessment tool/checklist for institutions handling high consequence agents and toxins developed by 2021 (Type: Intervention Logic)	KIIs	Final checklist/toolkit				
JC.6.2	Training and availability of assessors and trainers						
I-6.2.1	Number of Regional Training of trainers on the minimum standards for high containment facilities by 2023 (Type: Intervention Logic)	KIIs	Training reports				
I-6.2.2	Number of trainers trained on the minimum standards for high containment facilities by 2023 (Type: Intervention Logic)		Training records				
I-6.2.3	Number of regional training and certification of assessors by 2023 (Type: Intervention Logic)	KIIs	Training reports				
I-6.2.4	Number of certified assessors trained through the Regional Centres of Excellence (RCoEs) by 2023 (Type: Intervention Logic) KIIs Training records						
JC.6.3	Institutional assessment, certification, and performance						
I-6.3.1	Number of institutions handling high consequence agents and toxins with assessments for compliance to standards conducted by 2025 (Type: Intervention Logic)	KIIs	Assessment reports				
I-6.3.2	Number of institutions that have received certification to handle high consequence agents and toxins by 2025 (Type: Intervention Logic)	KIIs	Certification records, formal letters				
I-6.3.3	Increase in the percentage of high-risk pathogen handling facilities demonstrating improved biosafety and biosecurity capabilities based on assessment scores aligned to minimum standards by 2025 (Type: Intervention Logic)						
Data Collection Methods	KIIs, In-depth Interviews, FGDs, Surveys						

EQ7 - System Strengthening and Global Alignment	Q7. To what extent has the BSBS Strategic Plan contributed to strengthening sustainable biosafety and biosecurity systems across Member States, including alignment with international frameworks (e.g., IHR, BWC, UNSCR 1540)?						
Rationale and Coverage	Reviews long-term systems-level improvements and alignment with international obligations.						
Evaluation Criteria covered:	Impαct						
Specific Evaluation Questions	 Are international obligations met? Are BSBS elements integrated into national systems? Is there evidence of sustainability? 						
Judgement criteria and india	cators	Data sources					
JC.7.1	Alignment with international BSBS frameworks and standards						
I-7.1.1	Proportion of Member States (MS) with JEE score ≥3 for biosafety and biosecurity (P.7.1 & P.7.2)	KIIs	WHO JEE Mission Reports				
I-7.1.2	Proportion of MS reporting atleast Level 3 for C.4.2 in SPAR	KIIs	WHO SPAR Reports				
I-7.1.3	Proportion of Member States reporting alignment with international BSBS frameworks (Type: Adapted)	Surveys	National reports				
I-7.1.4	National strategic plans referencing IHR/BWC/UNSCR 1540 compliance (Type: Adapted)	National strategic plans referencing IHR/BWC/UNSCR 1540 compliance (Type: Adapted) KIIs Strategic plans					
JC.7.2	Institutional ownership						
I-7.2.1	Dedicated budget lines for BSBS implementation at national level (Type: New)	FGDs	National budgets				
I-7.2.2	Presence of BSBS focal units within MoHs or NPHIs (Type: New) KIIs Organizational char						
JC.7.3	Sustainability readiness	Sustainability readiness					
I-7.3.1	Reports of continued BSBS activity post-donor support (Type: New)	ports of continued BSBS activity post-donor support (Type: New) KIIs Program reviews					
I-7.3.2	overnment-issued policy briefs sustaining BSBS investment (Type: New) FGDs Policy records						
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys						

EQ8 - Sustainability of Investments	Q8: Are the investments in training, legal framework development, and regional assessments likely to be institutionalized within Member States or dependent on continued external support?						
Rationale and Coverage	Explores whether the BSBS gains are embedded or reliant on external inputs.						
Evaluation Criteria covered	: Sustainability, Implementation						
Specific Evaluation Questions	 Are systems ready to sustain gains? Are institutional structures in place? What risks exist for backsliding?						
Judgement criteria and ind	icators	Data sources	i				
JC.6.1	Development of certification tools and regulatory framework	Development of certification tools and regulatory framework					
JC.8.1	National ownership	Primary	Secondary				
I-8.1.1	Presence of BSBS focal points in national systems (Type: New)	KIIs	HR records				
I-8.1.2	Budget allocations for BSBS capacity building (Type: New)	Budget allocations for BSBS capacity building (Type: New) FGDs Budget reports					
JC.8.2	Institutionalization of tools						
I-8.2.1	Integration of BSBS legal framework into national regulations (Type: New)	KIIs	Legal texts				
I-8.2.2	Existence of SOPs derived from AU regional tools (Type: New)	Existence of SOPs derived from AU regional tools (Type: New) KIIs Operational manuals					
JC.8.3	Dependency on external support						
I-8.3.1	MS reporting reliance on Africa CDC for BSBS strategy updates (Type: New)	MS reporting reliance on Africa CDC for BSBS strategy updates (Type: New) Surveys Support request logs					
I-8.3.2	Institutional capacity gaps preventing transition to full ownership (Type: New) FGDs Capacity assessment summaries						
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys						

EQ9 - Implementation Challenges and Mitigation	Q9: What were the main operational, institutional, or external challenges that affected the implementation of the BSBS Strategic Plan, and how were they addressed across different levels of the system (e.g., Africa CDC, RCCs, Member States, partners)?						
Rationale and Coverage	Captures practical and institutional challenges faced during implementation and miti	gation efforts.					
Evaluation Criteria covered: (Challenges, Implementation						
Specific Evaluation Questions	 What were the most common implementation challenges? Were they addressed effectively? What were the lessons? 						
Judgement criteria and indic	ators	Data sources					
JC.9.1	Operational delays	Primary	Secondary				
I-9.1.1	Reported implementation delays in activity rollouts (Type: Adapted)	KIIs	Activity reports				
I-9.1.2	Procurement and staffing issues encountered (Type: New) FGDs Operations log						
JC.9.2	Systemic and institutional constraints	Systemic and institutional constraints					
I-9.2.1	MS citing role ambiguity or unclear mandates (Type: New)	MS citing role ambiguity or unclear mandates (Type: New) Surveys Organizational reviews					
I-9.2.2	Lack of coordination among implementing agencies (Type: New)	ack of coordination among implementing agencies (Type: New) KIIs Coordination reviews					
JC.9.3	Mitigation responses						
I-9.3.1	Adaptations made to address delays (Type: New)	daptations made to address delays (Type: New) KIIs Activity amendments					
I-9.3.2	essons from RCCs and Africa CDC shared in reports (Type: Adapted) FGDs Internal reviews						
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys		,				

EQ10 - Strategic Learning and Recommendations	Q10: What key lessons from the implementation of the 2021–2025 Strategic Plan should shape the design, theory of change, and priorities of the next BSBS Strategy (2025–2030)?						
Rationale and Coverage	Draws on practical experiences to inform the next phase of strategic planning.						
Evaluation Criteria covered:	Lessons Learned, Recommendations						
Specific Evaluation Questions	·						
Judgement criteria and indic	cators	Data sources					
JC.10.1	Reflections on successful practices	Secondary					
I-10.1.1	Practices reported by MS as effective in implementation (Type: Adapted)	KIIs	Success stories				
I-10.1.2	Examples of high-performing partnerships (Type: Adapted)	Examples of high-performing partnerships (Type: Adapted) FGDs Partner activity logs					
JC.10.2	Identified gaps and misalignments						
I-10.2.1	Documentation of underperforming interventions (Type: New)	KIIs	Mid-term reviews				
I-10.2.2	Stakeholder feedback on strategy alignment (Type: Adapted) Surveys Surveys summaries						
JC.10.3	Recommendations for future planning						
I-10.3.1	Suggestions for strategic themes in 2025–2030 plan (Type: Adapted) FGDs Strategic workshops						
I-10.3.2	heory of change improvements proposed by MS and partners (Type: Adapted) KIIs Planning memos						
Data Collection Methods	Desk reviews, KIIs, In-depth Interviews, FGDs, Surveys						

Annex 3: Full Detailed Evaluation Methodology

6.2 Evaluation Methodology

The methodology for this end-term evaluation of the BSBS 5-Year Strategic Plan (2021-2025) was designed to respond to the objectives and expectations outlined in the scope of evaluation while ensuring methodological rigor, stakeholder inclusiveness, and contextual relevance. It built on a theory-informed and utilization-focused approach, aligned with key OECD-DAC evaluation criteria-namely, effectiveness, impact, and sustainability and integrated cross-cutting issues such as implementation challenges, lessons learned, and strategic recommendations.

The evaluation adopted a mixed-methods design, combining qualitative and quantitative data collection techniques. This approach ensured comprehensive coverage of institutional, regional, and national experiences, while enabling triangulation across different sources of evidence. The methodology was structured around the EQs and matrix developed during the inception phase and was tailored to accommodate the complexity of BSBS implementation across multiple levels and actors. This section outlines the key elements of the evaluation methodology, including data collection methods, data sources, sampling strategy, data analysis plans, ethical considerations, and limitations.

6.2.1 Data collection methods

The evaluation employed a multi-method data collection approach, ensuring a comprehensive assessment. Data was collected from both primary and secondary sources and the evaluation used a mix of qualitative and quantitative methods to enable triangulation and ensure depth and breadth of analysis. Core methods included desk reviews, Key Informant Interviews (KIIs), In-depth Interviews (IDIs), Focus Group Discussions (FGDs), and surveys. These methods were tailored to the type of stakeholder, level of engagement, and evaluation question being addressed. Key evaluation methods used are described below.

6.2.1.1 Desk Review

The desk review is an integral part of the inception phase and was conducted to establish a strong foundation for the evaluation. The purpose was to gain a thorough understanding of the strategy's design, scope, implementation context, and performance monitoring to inform the evaluation questions, matrix, and data collection tools. It assessed the availability and quality of existing data, and identified key themes, outputs, and implementation modalities that informed the evaluation design, sampling, and line of inquiry. It involved systematic reviewing of key documents and technical outputs related to the design, implementation, monitoring, and coordination of the BSBS 5-Year Strategy (2021-2025).

The documents reviewed listed in Annex 3 include;

- The Africa CDC BSBS 5-Year Strategic Plan (2021-2025)
- Biosafety and Biosecurity Initiative Progress Reports
- Country Joint External Evaluation Reports
- Country State Party Self-Assessment Annual Report
- Global Health Security Index
- · Country Reports related to implementation of BSBS
- Other relevant implementing partners BSBS progress reports
- BSBS related publications

The desk review informed the reconstruction of the intervention logic, refinement of indicators, and the evaluation matrix. Additional documents were reviewed during tool development and prior to data collection to further validate findings and ensure alignment with implementation realities. The desk review resulted into identification of gaps, inconsistencies and areas where the strategy succeeded or faced challenges. The method supported indicator validation, baseline/target verification, and triangulation with primary data. Focus was on; quantitative comparison which involved comparison of baseline figures with end-line figures for numerical indicators such as number of staff trained as well as qualitative assessment which was done for non-numerical indicators, like changes in staff knowledge. Methods like interviews, FGDs or surveys were used to assess whether training and awareness activities were successful.

6.2.1.2 Qualitative methods

Qualitative methods form a core component of the evaluation's data collection strategy, enabling the exploration of context, perceptions, institutional experiences, and nuanced understanding of implementation dynamics that cannot be captured through quantitative means alone. These methods are particularly well suited to assess the relevance, effectiveness, coordination, and sustainability of the BSBS Strategic Plan from the perspective of diverse stakeholders.

Through KIIs, IDIs, and FGDs, the evaluation engaged with actors at the continental, regional, and national levels. These included representatives from Africa CDC, RCCs, NPHIs, NRLs, RBB-TWGs, ministries, and key development partners. The qualitative approach was designed to ensure inclusion of both strategic leadership and operational voices, allowing the evaluation to assess not only what was achieved, but how and why certain outcomes were or were not realized. The insights generated through qualitative data was triangulated with desk review and quantitative survey findings to strengthen the reliability and depth of the evaluation's conclusions. The interviews were conducted through virtual platforms.

Key Informant Interviews (KIIs); They were used as a primary qualitative method to collect in-depth insights from individuals who have been directly involved in or closely engaged with the implementation of the BSBS 5-Year Strategic Plan (2021-2025). These stakeholders occupy positions that offer strategic, institutional, or technical perspectives on the design, coordination, and results of the strategy at continental, regional, and national levels. Interviews were conducted using semi-structured guides shared in Annex 4 aligned with the evaluation questions and matrix. Target respondents included staff from Africa CDC, RCCs, NPHIs, RBB-TWGs, ministries, and selected development partners.

The KIIs also contributed to triangulating data collected through document review, focus group discussions, and surveys, enhancing the depth and credibility of the evaluation findings. Key stakeholders such as program managers, policy makers, decision makers, international consultants, funding organisations who have specialised in-depth knowledge about BSBS initiative or are in key positions relevant to the initiative were considered. The expected output was a deeper understanding of strategic level outcomes and program effectiveness from people who have a broad understanding of the BBI, its overall achievements, challenges, and broader implications.

In-depth Interviews (IDIs); They served as a key qualitative method to explore detailed, experience-based perspectives from individuals who were directly involved in implementing specific components of the BSBS 5-Year Strategic Plan (2021-2025). These included individuals directly involved in the operational and practical aspects of the BBI. They perform the activities which execute the strategic plan on the ground. Unlike Key Informant Interviews, which target strategic-level stakeholders, IDIs focused on operational and technical-level actors who provided rich, first-hand insights into what was implemented, how, and with what results. The aim was to gather information on how the activities

were executed, the practical barriers faced, and any other unintended consequences or unexpected successes. There was a need to understand the personal experiences and detailed stories about the implementation process.

Target respondents included focal persons from NPHIs, NRL, biosafety and biosecurity program Leads, biosafety officers, laboratory managers and technical experts engaged in training, assessments, or coordination at national or regional levels. The IDIs followed a semi-structured format, allowing for flexibility to probe specific interventions, implementation challenges, and perceived outcomes. Data collected through IDIs was triangulated with findings from KIIs, document reviews, and surveys to ensure a comprehensive and credible evaluation. This approach allowed the evaluation to explore complex themes and uncover practical lessons learned from those directly involved in operationalising the Strategic Plan. See Annex 5 for the IDI guide.

Focus Group Discussions (FGDs); They were employed as a qualitative method to capture collective insights, shared experiences, and group dynamics among stakeholders involved in the implementation of the BSBS 5-Year Strategy (2021–2025). The FGDs primarily targeted members of RBB-TWGs. Other local stakeholders who are involved in the operational or field-level implementation of biosafety and biosecurity measures were considered for example, frontline staff, laboratory technicians, local health workers, trained personnel and other implementers at the regional and national levels. This enabled collective views and opinions from groups of stakeholders to be gathered. The group format enabled participants to reflect together on their experiences, validate one another's contributions, and identify areas of consensus or divergence on implementation progress, challenges, and lessons learned. Each discussion was guided by a semi-structured FGD guide provided in Annex 6 aligned with the evaluation matrix. FGDs were conducted virtually, and were designed to ensure inclusive participation across regions, institutions, and levels of expertise. Insights from FGDs were triangulated with data collected through key informant interviews, in-depth interviews, desk reviews, and surveys to support robust and well-rounded findings. The outputs involved identification of common themes, issues, and challenges in BSBS practice at the operational level.

6.2.1.3 Ouantitative methods

Quantitative methods were used to generate measurable data on the reach, effectiveness, and perceived outcomes of the BSBS 5-Year Strategy (2021-2025). The primary quantitative tool was an online survey targeting a broad sample of trained personnel, technical working group members, national focal points, and public health professionals. The survey provided standardized data to complement qualitative findings, allowing for trend analysis, regional comparison, and aggregation of stakeholder perspectives across Member States.

6.2.1.4 Surveys and questionnaires

Surveys were used as a quantitative data collection method to gather standardized information from a broad range of stakeholders across AU Member States. The survey captured the extent of participation in BSBS activities, perceived changes in institutional capacity, satisfaction with technical support, and views on sustainability and future priorities. The survey targeted individuals who were involved in or affected by BSBS interventions, including trained staff, members of RBB-TWGs, national focal points, laboratory personnel, and public health professionals. It was administered through distribution of structured online surveys which allowed for wide geographic reach and efficient data management. The questionnaire was developed in English and subsequently translated into French to ensure accessibility for stakeholders across the African Union Member States, see Annex 7.

The questionnaire included both closed-ended and open-ended questions aligned with the EQs and judgment criteria in the evaluation matrix. Quantitative responses were allowed for aggregation and comparative analysis across regions and stakeholder groups, while open-ended responses provided

additional qualitative insights. The survey data was triangulated with findings from interviews, FGDs, and desk reviews to ensure a comprehensive analysis of the BSBS Strategic Plan's implementation and impact.

Surveys used Likert-scale questions to measure attitudes or satisfaction, closed and open-ended questions to gather quantitative and qualitative feedback. The outputs included the quantitative data which was be analyzed statistically, and that was complemented by qualitative responses to explore issues in more depth. The survey was done after gathering qualitative insights from interviews so as to validate and quantify these findings across a broader population.

The survey was not structured around individual-level KPIs. Instead, it was aligned with the evaluation matrix and intervention logic to gather relevant feedback from stakeholders involved in BSBS implementation. While most KPIs were institutional or programmatic, the survey focused on perceptions of coordination, tool uptake, and training impact to complement broader evaluation findings.

6.2.1.5 Benchmarking and comparison

The purpose of this component was to compare the outcomes and progress of the BSBS Strategic Plan with other similar BSBS programs and international standards. This was carried out by identifying peer initiatives and frameworks — including those from WHO, the Global Health Security Agenda (GHSA), and national-level biosafety programs — and reviewing their strategic goals, methods of implementation, and achievements.

One specific comparative case used was the ASEAN Regional Strategic and Action Plan for Biosafety and Biosecurity (2019–2023), which shares similar objectives with the BSBS strategy. The ASEAN framework focuses on regional harmonization, One Health integration, capacity building, and laboratory biorisk management systems. Lessons drawn from the ASEAN experience informed the evaluation's assessment of regional coordination platforms, legal domestication processes, and multisectoral alignment.

Outputs from this activity included comparative observations of program design, implementation scope, and impact. The benchmarking helped identify areas where the BSBS initiative aligns well with global standards and where further adaptation or scaling may be needed. The benchmarking helped identify areas where the BSBS initiative aligns well with global standards and where further adaptation or scaling may be needed.

6.2.1.6 SWOT Analysis

As part of the overall analysis, a SWOT (Strengths, Weaknesses, Opportunities, Threats) framework was applied to synthesize internal and external factors that influenced the implementation and impact of the BSBS Strategic Plan. The SWOT analysis drew from coded qualitative data, survey responses, and document review to identify patterns of institutional and strategic performance. Strengths and weaknesses reflected internal attributes (e.g., Africa CDC coordination, training quality), while opportunities and threats reflected external factors (e.g., political buy-in, donor dependency). This analysis informed the conclusions and recommendations sections and was used to prioritize areas for strategic focus in the next planning cycle.

Table 4: Main findings of the SWOT analysis conducted as part of this evaluation

Strengths

Strong Africa CDC leadership and convening power Well-received tiered training and certification model Availability of technical tools and assessment checklists Regional TWG structures facilitated coordination

Weaknesses

Inconsistent institutional readiness and staffing gaps
Limited post-training mentorship and follow-up
Language barriers and delays in material translation
Lack of formal institutionalization in many Member States

Opportunities

Integrate BSBS into national budgets and organograms Leverage existing training platform to reach other sectors Promote career development pathways for BSBS professionals Scale up certification to more labs and institutions

Threats

Ongoing donor dependency in many countries Risk of momentum loss post-strategy period Political turnover and competing priorities Low awareness in non-human health sectors

Through the employment of a combination of these methods, a comprehensive evaluation of the BBI, addressing both its strategic impacts and its operational outcomes will be effectively conducted.

6.2.2 Data sources

The evaluation was draw on both primary and secondary data sources to ensure a comprehensive, credible, and triangulated evidence base. Primary data was collected directly from key stakeholders involved in the design, implementation, and oversight of the BSBS 5-Year Strategic Plan (2021-2025). This included Africa CDC staff, RCCs, NPHIs, NRL, members of RBB-TWGs, public health professionals, and development partners as listed in Annex 8. Primary data was gathered through KIIs, IDIs, FGDs, and an online survey targeting a broad group of trained personnel and national focal points. Secondary data sources included relevant documentation such as the BSBS Strategic Plan, the M&E framework, annual progress and activity reports, strategic and legal framework drafts, training records, meeting minutes, technical guidelines, assessment reports, and related partner publications. These documents provided background context, support indicator verification, and enable comparison of baseline, target, and actual performance data across the strategy period.

6.2.3 Sampling Strategy and Stakeholder Engagement

The evaluation adopted a purposive, multi-level sampling strategy designed to ensure broad and meaningful engagement with stakeholders across all five Africa CDC RCCs and at the continental, regional, and national levels. The sampling was structured to align with the evaluation's mixed-methods design, which includes KIIs, IDIs, FGDs, and an online survey.

Stakeholders were initially categorized into groups based on their roles in the design, implementation, coordination, or oversight of the BSBS Strategic Plan. These include:

- Africa CDC headquarters staff (strategy leads, technical focal points, M&E, legal)
- Regional Coordinating Centre (RCC) representatives
- National Public Health Institutes (NPHIs), national reference laboratories, and trained technical personnel
- Members of the Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs)
- Relevant ministries (Health, Agriculture, Environment) involved in national implementation
- Development partners and donors supporting biosafety and biosecurity in Africa

A preliminary stakeholder map informed the sampling approach, but the list of specific individuals and institutions was refined and finalized during the data collection planning phase, in close consultation with Africa CDC and RCC focal points. This staged approach allowed for ensuring that all relevant voices were captured, while maintaining flexibility to accommodate emerging information, regional access, and the evolving institutional landscape.

6.2.3.1 Qualitative Sampling Strategy

A purposive, stakeholder-based sampling approach was used for qualitative data collection, including KIIs, IDIs, and FGDs. The purposive sampling approach ensured inclusion of strategic, technical, and field-level actors. Participants were selected based on their institutional roles, level of involvement in the BSBS Strategic Plan, and ability to provide relevant insights on implementation, coordination, and outcomes.

For this end-term evaluation of a BBI 5-year strategic plan involving a full evaluation across five regions, determining the sufficient number of participants for each interview type depended on several factors such as the type of stakeholders being interviewed, the diversity of regions, and the depth of data to be collected. However, in qualitative research, the focus is on achieving data saturation, so the plan was to conduct enough interviews to reach a point where no new significant information is emerging. The number of interviews and focus group discussions was determined based on the diversity of stakeholder roles, regional representation, and the evaluation's need for triangulation. Planned numbers were indicative and were adjusted based on feasibility and emerging information needs as shown below. There was language interpretation provided by ASLM for those who needed it during the interviews.

The qualitative sample included:

Key Informant Interviews

The number of KIIs planned per region varies based on the size of the regional cluster and the number of AU Member States (MS) it encompassed. Based on the 5 RCCs with varying numbers of MS, regions with more MS (such as the Eastern and Western RCCs) had a proportionally higher number of KIIs to ensure adequate stakeholder representation and geographic diversity. Additionally, institutional density, the level of coordination roles played by RCCs, and the availability of regional partners and

technical actors further influenced the distribution. The allocation also considered logistical feasibility, language diversity, and the need to triangulate perspectives from both regional institutions and national-level actors. While the KII targets were indicative, they remained flexible and were adjusted based on stakeholder availability and the quality of responses received during data collection. The plan was to conduct 30 KIIs however 42 KIIs were conducted with key informants at Africa CDC, RCCs, national institutions, and development partners. Stakeholders included; representatives from Africa CDC secretariat and ASLM, funders including Global Affairs Canada, the World Bank and the Coalition for Epidemic Preparedness Innovations; and the rest of the KIIs were distributed across the 5 RCCs including government officials and previous chairs of the RBB-TWGs.

In-depth Interviews

The selection of the IDIs were purposive and conducted while carefully selecting individuals who possessed deep technical expertise and first-hand experience with the implementation of the BSBS Strategic Plan. Participants were identified in collaboration with Africa CDC and RCC focal points, ensuring diversity in roles, institutional affiliation, and technical domains.

An initial target of 40 In-depth Interviews was set to ensure adequate representation across diverse country-level implementers and stakeholders however 29 IDIs were conducted. The final number of IDIs was determined based on the principle of information saturation whereby interviews continued until no new themes emerged. The number of In-depth Interviews planned per region varied based on the size of the regional cluster and the number of AU Member States (MS) it encompasses. Stakeholders were drawn from the Africa CDC secretariat and across the five RCCs and the proposed were; technical officers from Africa CDC secretariat, coordinators of the Regional Centres of Excellence (RCoEs) and a team-lead of the ASLM Academy. In order to ensure adequate representation, the remaining interviews were conducted among biosafety officers, laboratory managers at the NRLs, focal persons from NPHIs and One Health/biosecurity focal points from the 5 RCCs based on the presence and engagement of relevant institutions and actors.

Focus Group Discussions

FGDs were used to gather collective insights from stakeholders actively involved in the implementation of the BSBS Strategic Plan at various levels. Participants were purposively selected based on their shared roles, functions, or experiences, to allow for meaningful group dialogue around specific thematic areas such as capacity building, coordination mechanisms, institutional challenges, and cross-sectoral collaboration.

A total of 10 FGDs were planned and due to the small number of FGDs, a modified proportional approach was used to ensure both representation and practicality, with every RCC included and larger regions slightly more represented. Participants included mid-level technical officers, laboratory personnel, public health workers, and representatives from animal and plant health sectors. Where appropriate, FGDs were group participants by institutional type or technical area to enhance relevance and comfort in discussing shared experiences. Each FGD was planned to comprise 6 to 8 participants, selected in coordination with RCC focal points and relevant institutions. The groups proposed include; members of the RBB-TWGs, laboratory technicians, trained personnel, biosafety focal points and mid-level technical officers such as from NPHIs, Ministry of Health or other government agencies. However, it was a great challenge to organise an FGD with the recommended number, of the 7 we had, the composition ranged from (1-6) due to reasons such as internet challenges, competing priorities among others.

6.2.3.1 Quantitative Sampling Strategy

The quantitative component of the evaluation was conducted through an online survey using Kobocollect targeting a broad cross-section of stakeholders involved in the implementation of the BSBS Strategic Plan across the Africa CDC Secretariat, RCCs, NPHIs, NRLs, and relevant animal and plant health sectors. Respondents included individuals in technical, programmatic, and policy-related roles who have directly or indirectly contributed to or interacted with BSBS activities during the implementation period. A French translated version of the survey form was provided.

A non-probability purposive sampling approach was employed, aiming to reach as many relevant stakeholders as possible across the five regions. This approach ensured that deep insights were obtained from people with specialized knowledge or who had been involved in or supported the BBI because their insights are directly relevant to the evaluation questions. The survey was disseminated through established Africa CDC and RCC communication channels, leveraging institutional mailing lists, partner networks, and technical working groups to ensure wide coverage. The survey distribution was proportionally balanced across RCCs to support regionally representative findings. It was distributed to participants from the Africa CDC Secretariat, ASLM, RBB-TWGs, NPHIs, NRLs, relevant Ministries such as Health, Agriculture and implementation partners.

Given the evaluation's emphasis on broad participation rather than statistical generalizability, no fixed sample size was determined beforehand. Instead, the focus was on maximizing reach and participation across countries and stakeholder groups. However, to ensure meaningful analysis and strong regional representation, the survey aimed to achieve a minimum of 300 completed responses in total. This was to allow for disaggregation by region, institution type, and technical area, and to strengthen the reliability of quantitative findings. In some cases, individuals participated in both an interview and the online survey. This dual participation was intentional, as it allowed for triangulation of perspectives and deeper contextual understanding. Measures were taken to manage data overlap and ensure the integrity of both data sets. Survey distribution across the five RCCs was estimated based on the number of countries in each region, as a proxy for relative stakeholder volume. Regional allocations were proportionally adjusted from a pool of 270 surveys, with 30 reserved for Africa CDC Secretariat and cross-regional partners. Table 5 shows the relevant stakeholder groups.

Table 5: Key Stakeholder Groups Relevant to the Evaluation of the BSBS Strategic Plan

Stakeholder Group	No. of countries	Planned KIIs	Adjusted KIIs	Actual KIIs	Planned IDIs	Adjusted IDIs	Actual IDIs	Planned FGDs	Actual FGDs	Surveys (Estimates)	Actual Nos.
Western RCC	15	7	8	8	9	8	10	3	2	65	34
Eastern RCC	14	6	7	7	9	8	9	3	1	59	25
Southern RCC	10	5	5	5	6	5	3	2	2	54	30
Central RCC	9	3	5	5	6	5	3	1	1	49	30
Northern RCC	7	3	3	3	4	4	4	1	1	43	42
Africa CDC secretariat,	N/A	6	12	14	6	0	0	0	0	30	0
ASLM & partners											
Total	55	30	40	42	40	30	29	10	7	300	199

6.2.4 Data Analysis Plan

The evaluation applied a mixed-methods approach, integrating both qualitative and quantitative data to assess the relevance, effectiveness, coordination, and outcomes of the Biosafety and Biosecurity Strategic Plan (BSBS). Analysis was structured around the evaluation questions, judgment criteria, and indicators outlined in the evaluation matrix, including those drawn from the reconstructed intervention logic.

6.2.4.1 Quantitative Data Analysis

Quantitative data analysis was carried out on two main fronts:

Survey Data Analysis

Survey data was cleaned and analyzed using statistical software such as Excel, Epi Info, SPSS or STATA. Descriptive statistics including frequencies, means, medians and percentages were used to summarize stakeholder perspectives on the effectiveness, implementation, impact, lessons learned and challenges of the BSBS Strategic Plan. Responses were disaggregated by region (RCC), sector, and institutional level (national, regional, continental, institutional). Cross-tabulations may be conducted to explore relationships between stakeholder attributes and their perceptions.

Indicator-Based Analysis (from Intervention Logic)

Quantitative data linked to the indicators defined in the reconstructed intervention logic were specifically analyzed to assess achievement against targets. Where baseline and target values existed (for both output and outcome indicators), actual progress was measured and expressed as a percentage of achievement.

This includes:

- Tracking the number and type of institutions supported
- Measuring the extent of implementation of BSBS policies or guidelines
- Assessing reported changes in technical or institutional capacity
- Summarizing key performance metrics (e.g., % of RCCs/NPHIs with risk management frameworks)

Indicator results were analyzed against the planned results chain to assess both direct outputs and intermediate outcomes, and were synthesized in tables and dashboards to show variations across regions or institutional types.

6.2.4.2 Qualitative Data Analysis

Qualitative data from Key Informant Interviews (KIIs), In-depth Interviews (IDIs), and Focus Group Discussions (FGDs) were transcribed and imported into ATLAS.ti for structured thematic analysis. A codebook was developed based on the evaluation matrix, with codes aligned to each evaluation question and associated judgment criteria. Additional inductive codes were added to capture emerging themes and unanticipated insights from participants. Coding was conducted iteratively, and key quotations were extracted for synthesis. Each Priority Area was analyzed separately, allowing for comparative insights across regions, institutional levels, and stakeholder types. Final thematic outputs were mapped back to the intervention logic to assess linkages between inputs, activities, outputs, and outcomes. Verbatim quotes were selected to illustrate core findings and variation in perspectives. This approach supported triangulation with survey and document review data, and ensured a rigorous and grounded analysis of implementation and results.

ATLAS.ti software was used to generate themes and sub-themes on the data. Data was coded, a codebook developed in ATLAS.ti and extracted into Microsoft word text, and responses were categorized into themes and subthemes. Thereafter interpretations were made. Thematic coding enabled comparison across regions (RCCs), stakeholder types, and technical domains. Representative quotes were extracted to illustrate findings, explain variations, and validate quantitative trends. The evaluation focused on capturing results across six Priority Areas (PAs) of the BSBS Strategy and used a reconstructed intervention logic and final evaluation matrix as analytical anchors.

Priority Area Group Mapping

Code Group Name	EQs to Add	Code Prefixes
PA1_StrategicFocus_AfricaCDC	EQ1, EQ2, EQ10	EQ1_, EQ2_, EQ10_
PA2_TWG_RegionalCoordination	EQ2, EQ4	EQ2_, EQ4_
PA3_Legal_Framework	EQ5	EQ5_
PA4_HCAT_Certification	EQ6	EQ6_
PA5_Training_Certification	EQ3	EQ3_
PA6_Strengthening_MS_Capacity	EQ1, EQ6, EQ7, EQ8	EQ1_, EQ6_, EQ7_, EQ8_

6.2.4.3 Triangulation and Integration

Qualitative and quantitative findings were triangulated to validate results and build a comprehensive picture of the program's performance. For each evaluation question, data from interviews, FGDs, surveys, and the indicator tracking analysis was synthesized. This helped contextualize numeric trends, explain variations, and enhance the credibility of conclusions.

6.2.4.4 Findings, Interpretation and Reporting

The presentation of findings was described by the Six BSBS Priority Areas structured around the evaluation questions and aligned with the judgment criteria and indicators outlined in the evaluation matrix. Quantitative results were presented using descriptive statistics, summary tables, and graphs, while qualitative data was synthesized thematically and supported with illustrative quotes. Findings were interpreted in relation to the Strategic Plan's Theory of Change and the reconstructed intervention logic. Particular attention was paid to variations across RCCs, stakeholder groups, and technical domains. The analysis also considered contextual factors and assumptions that may have influenced implementation or results.

Triangulation of quantitative and qualitative data supported robust interpretation and ensured that conclusions were evidence-based. Data visualisation including summary tables, charts, and quotes were created to support key findings. Recommendations were directly informed by the findings and clearly linked to observed trends, gaps, and opportunities for future strategic planning.

Report Structure and Organization

The evaluation report is structured around the six Priority Areas of the Africa CDC BSBS Strategy (2021–2025). This thematic organization was chosen to ensure direct alignment with the Strategic Plan itself, as well as with the evaluation questions and the reconstructed intervention logic. Each Priority Area is analyzed in terms of its effectiveness, implementation progress, early signs of impact, and sustainability, drawing on both quantitative and qualitative data sources. While the report does not follow a strict input—output—outcome—impact format, it provides a comprehensive results-oriented synthesis that addresses the full results chain in a format more suitable for strategic-level evaluation.

This approach enables clearer insight into what worked, what challenges emerged, and what can be strengthened in the next strategy phase.

6.2.5 Ethical Considerations

The evaluation adhered to standard ethical principles, ensuring that all participants were treated with respect, dignity, and confidentiality. Informed consent was obtained from all respondents, who were clearly informed about the purpose of the evaluation, their rights, and the voluntary nature of participation. Participants were allowed to decline to answer questions or withdraw at any time without consequence.

All data was used solely for the purpose of this evaluation. Data was anonymized during analysis and reporting, and all information was stored securely to protect participant privacy. The principle of "do no harm" was applied, taking care to avoid any form of psychological, professional, or reputational harm. The evaluation was conducted with full respect for the dignity, rights, and cultural context of all stakeholders involved especially during interviews and group discussions.

6.2.6 Limitations and Mitigation Strategies

While every effort was made to ensure a comprehensive, inclusive, and high-quality evaluation process, several potential limitations were anticipated. These are outlined Table 5 below, along with corresponding strategies to mitigate their impact. This approach ensured that potential challenges were acknowledged and addressed, supporting the credibility, inclusiveness, and usability of the evaluation findings.

Table 6: Anticipated Limitations and Corresponding Mitigation Strategies for the Evaluation

Potential Limitation	Mitigation Strategy
Non-response or Low Survey Participation	Disseminate the survey through trusted institutional channels and RCC focal points Send timely reminders to encourage participation Ensure the survey is brief, user-friendly, and accessible across devices Clearly communicate the purpose and importance of the evaluation
Limited Availability of Key Informants	Schedule interviews well in advance with flexible timing options Offer alternatives such as written responses or shorter interviews Identify and engage equally knowledgeable alternate respondents where necessary
Uneven Regional Representation	Collaborate closely with RCC focal points to encourage balanced outreach Monitor participation levels in real-time and increase follow-up in underrepresented regions Ensure language and contextual relevance of tools to improve accessibility
Limited Access to Secondary Data and Documentation	Request key documents early through formal channels. use qualitative insights to supplement gaps Cross-check with key informants and partners to fill documentation gaps
Potential Bias in Self- Reported Data	Ensure anonymity in survey responses to encourage honesty Triangulate self-reported data with multiple sources (e.g., program records, multiple perspectives) Use neutral, non-leading language in tools and probes
Language or Terminology Barriers	Pre-test tools to ensure clarity Use standardized definitions where possible Provide explanations during interviews or survey

Annex 4: Key Informant Interview Guides

A. Key Informant Interview (GENERIC)

This guide is designed to support Key Informant Interviews (KIIs) for the end-term evaluation of the BSBS 5-Year Strategic Plan (2021–2025).

In collaboration with several partners, Africa CDC held a series of consultative workshops to determine the status of biosafety and biosecurity capacity implementation continent wide and develop a set of regional priorities to address capacity gaps. Africa CDC developed a Five-Year Strategic Plan (2021-2025) to address these priority areas, using a regional approach. Africa CDC is leading end of BSBS 5-Year Strategic Plan (2021-2025) evaluation. The evaluation aims at determining the overall achievement of the BSBS Strategic Plan, identify lessons learned, challenges and make recommendations to inform the next 5-Year strategy.

Interviewer Instructions:

Probe based on the role of the respondent (Africa CDC, RCC, NPHI, Lab, or Partner). Start with informed consent and confirm permission to record if applicable.

Hello, my name is [Your Name], and I'm working with Freda Loy, the Lead Evaluator for the data collection as per the Monitoring and Evaluation Framework. She may engage with you directly during the data collection. She is expected to gather and summarize information provided by different sources and develop Draft report that will be reviewed and validated at the Regional Consultative Meeting 27-28 May 2025 in Addis Ababa. We greatly appreciate your consideration and support with information required.

The purpose of this interview is to understand your experiences and insights related to the implementation, outcomes, and lessons from the BSBS Strategic Plan. Your input will help assess what has worked, what challenges were faced, and what should be improved in the next phase of the strategy.

This interview will take approximately [45–60 minutes], and your participation is entirely voluntary. You may choose not to answer any question or to stop the interview at any time without penalty. Your responses will remain confidential. We will not include your name or any identifying information in the report. The information you share will be used only for the purposes of this evaluation.

With your permission, I would like to record this conversation to ensure accuracy. The recording will be securely stored and used only for analysis.

Do you have any questions before we begin?

If you agree to proceed with the interview, please confirm verbally that you consent.

EQ1: To what extent has the BSBS Strategic Plan improved technical and institutional capacity to prevent, detect, and manage biosafety and biosecurity risks?

Core Question:

To what extent has the BSBS Strategic Plan improved technical and institutional capacity to prevent, detect, and manage biosafety and biosecurity risks?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ2: To what extent has the BSBS Strategic Plan strengthened coordination and implementation capacity?

Core Question:

To what extent has the BSBS Strategic Plan strengthened coordination and implementation capacity?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ3: How effective was the regional training and certification program in improving competencies and application of skills?

Core Question:

How effective was the regional training and certification program in improving competencies and application of skills?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ4: To what extent have RBB-TWGs contributed to cross-country coordination and strategic alignment?

Core Question:

To what extent have RBB-TWGs contributed to cross-country coordination and strategic alignment?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ5: To what extent have Member States developed roadmaps to domesticate the AU BSBS Legal Framework, and what influenced uptake?

Core Question:

To what extent have Member States developed roadmaps to domesticate the AU BSBS Legal Framework, and what influenced uptake?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ6: What evidence exists that institutions have improved biosafety and biosecurity practices as a result of BSBS capacity-building?

Core Ouestion:

What evidence exists that institutions have improved biosafety and biosecurity practices as a result of BSBS capacity-building?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ7: To what extent has the BSBS Strategic Plan contributed to sustainable systems and international alignment?

Core Question:

To what extent has the BSBS Strategic Plan contributed to sustainable systems and international alignment?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ8: Are BSBS-related investments likely to be institutionalized within Member States or remain donor-dependent?

Core Question:

Are BSBS-related investments likely to be institutionalized within Member States or remain donor-dependent?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ9: What were the major implementation challenges and how were they addressed?

Core Question:

What were the major implementation challenges and how were they addressed?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ10: What lessons should inform the design and theory of change of the next BSBS Strategic Plan?

Core Question:

What lessons should inform the design and theory of change of the next BSBS Strategic Plan?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

B. KII Guide for Lawyer

EQ2: To what extent has the BSBS Strategic Plan strengthened coordination and implementation capacity?

Core Question:

To what extent has the BSBS Strategic Plan strengthened coordination and implementation capacity?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ4: To what extent have RBB-TWGs contributed to cross-country coordination and strategic alignment?

Core Question:

To what extent have RBB-TWGs contributed to cross-country coordination and strategic alignment? **Suggested Probes**:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ5: To what extent have Member States developed roadmaps to domesticate the AU BSBS Legal Framework, and what influenced uptake?

Core Question:

To what extent have Member States developed roadmaps to domesticate the AU BSBS Legal Framework, and what influenced uptake?

Suggested Probes:

- What steps have been taken to domesticate the AU BSBS Legal Framework?
- What has been the legal process followed in the supported countries?
- What factors have enabled or hindered domestication?

Legal-Specific Probes

Status & Process

- What is the current status of domestication in Member States you've supported?
- What legal instruments or mechanisms have been used (e.g., ministerial orders, bills, regulations)?

Drivers of Progress

 What factors have facilitated progress in legal domestication (e.g., political will, inter-ministerial coordination, donor support)?

Barriers

 What are the most common legal or institutional barriers Member States face in domesticating the AU framework?

Africa CDC's Role

• How effective has Africa CDC support been in facilitating the legal domestication process?

Harmonization

 To what extent are Member States aligning domestic laws with the AU BSBS Legal Framework and international standards?

Sustainability

 Once domesticated, what mechanisms exist (or are needed) to ensure implementation and enforcement?

Can you describe the planning and coordination efforts for regional advocacy meetings with Member States and partners to promote the biosafety and biosecurity legal framework — particularly at the start?

Follow-up Probes:

- Were these meetings held as planned? If so, when and where?
- Who were the key partners or Member State representatives involved?
- What were the main outcomes or commitments made during these meetings?

What is the progress in organizing high-level advocacy meetings with political or technical champions to support the legal framework?

Follow-up Probes:

- Who were identified as champions, and how were they engaged?
- What level of influence did these champions have on Member State uptake?
- Were there any particular success stories or setbacks?
- To what extent were these advocacy activities part of the broader strategy to support domestication of the AU BSBS Legal Framework?

EQ7: To what extent has the BSBS Strategic Plan contributed to sustainable systems and international alignment?

Core Question:

To what extent has the BSBS Strategic Plan contributed to sustainable systems and international alignment?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?
- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ8: Are BSBS-related investments likely to be institutionalized within Member States or remain donor-dependent?

Core Ouestion:

Are BSBS-related investments likely to be institutionalized within Member States or remain donor-dependent?

Suggested Probes:

- What activities or structures were introduced under this objective?
- What changes or improvements have you observed?

- What challenges were encountered?
- How do you assess the relevance and sustainability of the interventions?

EQ9: What were the major implementation challenges and how were they addressed?

Core Question:

What were the major implementation challenges and how were they addressed?

Suggested Probes:

- What challenges were encountered?

EQ10: What lessons should inform the design and theory of change of the next BSBS Strategic Plan?

Core Question:

What lessons should inform the design and theory of change of the next BSBS Strategic Plan?

C. KII Guide-IFBA

EQ3: Effectiveness of the Training and Certification Program

Core Question:

How effective was the regional training and certification program in improving competencies and application of skills?

Tailored Probes:

What role did IFBA play in supporting Africa CDC's training and certification strategy?

How were training modules or certification criteria developed, and were they adapted regionally?

What trends have you observed in certification uptake and competency development among African professionals?

What challenges did IFBA or implementing institutions face in rolling out certification at scale?

What innovations, tools, or partnerships helped to expand reach and impact?

How do you assess the sustainability of the training/certification model?

EQ7: Contribution to Sustainable Systems and International Alignment

Core Question:

To what extent has the BSBS Strategic Plan contributed to sustainable systems and international alignment?

Tailored Probes:

To what extent are IFBA certifications recognized and institutionalized in African countries?

Have you observed any movement toward integrating training/certification into national systems or policies?

How well does the Africa CDC training framework align with international biosafety and biosecurity standards?

What partnerships are most critical for sustainability moving forward?

Additional Questions

What lessons can Africa CDC draw from global biosafety certification efforts to inform the next Strategic Plan?

How might IFBA support greater localization or regional ownership of biosafety standards and training programs in Africa?

Annex 5: In-Depth Interview Guides

A. In-Depth Interview Guide (GENERIC)

This guide is intended for conducting In-depth Interviews (IDIs) as part of the end-term evaluation of the BSBS 5-Year Strategic Plan (2021–2025). It includes a structured consent script and core themes aligned with the evaluation questions.

In collaboration with several partners, Africa CDC held a series of consultative workshops to determine the status of biosafety and biosecurity capacity implementation continent wide and develop a set of regional priorities to address capacity gaps. Africa CDC developed a Five-Year Strategic Plan (2021-2025) to address these priority areas, using a regional approach. Africa CDC is leading end of BSBS 5-Year Strategic Plan (2021-2025) evaluation. The evaluation aims at determining the overall achievement of the BSBS Strategic Plan, identify lessons learned, challenges and make recommendations to inform the next 5-Year strategy.

Informed Consent

Hello, my name is [Your Name], and I'm working with Freda Loy, the Lead Evaluator for the data collection as per the Monitoring and Evaluation Framework. She may engage with you directly during the data collection. She is expected to gather and summarize information provided by different sources and develop Draft report that will be reviewed and validated at the Regional Consultative Meeting 27-28 May 2025 in Addis Ababa. We greatly appreciate your consideration and support with information required.

The purpose of this interview is to understand your experiences and insights related to the implementation, outcomes, and lessons from the BSBS Strategic Plan. Your input will help assess what has worked, what challenges were faced, and what should be improved in the next phase of the strategy.

This interview will take approximately [60–75 minutes], and your participation is entirely voluntary. You may choose not to answer any question or to stop the interview at any time without penalty. Your responses will remain confidential. We will not include your name or any identifying information in the report. The information you share will be used only for the purposes of this evaluation.

With your permission, I would like to record this conversation to ensure accuracy. The recording will be securely stored and used only for analysis.

Do you have any questions before we begin?

If you agree to proceed with the interview, please confirm verbally that you consent.

Interview Themes and Questions

Theme 1: Strategic Implementation

- Can you describe your institution's role in implementing the BSBS Strategic Plan?
- What were the main interventions or initiatives you were involved in?

Theme 2: Capacity Strengthening and Institutional Change

- Have you observed changes in technical or institutional capacity over the past five years?
- What contributed to those changes? What gaps remain?

Theme 3: Regional Coordination and Collaboration

- How has regional coordination (through RCCs, TWGs, etc.) supported your work?
- What have been the successes and challenges of cross-country collaboration?

Theme 4: Impact and Outcomes

- What have been the most significant results or outcomes from the BSBS strategy?
- How have these outcomes affected public health or institutional practices?

Theme 5: Sustainability and Ownership

- Are the activities or changes introduced by the BSBS strategy likely to continue without external support?
- What mechanisms are in place to ensure sustainability?

Theme 6: Lessons Learned and Future Directions

- What key lessons have emerged during the implementation of the strategy?
- What would you recommend for the next strategic plan?

B. IDI Guide Trainers

Theme 1: Training Delivery and Quality

- 1. Can you describe the biosafety and biosecurity training(s) you were involved in delivering?
- 2. How well adapted were the training materials and modules to the practical needs of the participants?
- 3. Were there any technical areas you feel were missing or underemphasized in the curriculum (e.g., emerging biosafety risks, synthetic biology, dual-use research)?

Theme 2: Trainee Engagement and Skill Application

- 4. From your observation, how well did trainees engage during the training sessions?
- 5. Have you observed whether trainees applied the skills and knowledge gained in their institutions after the training?
- 6. Were there noticeable differences in training uptake or application across regions, institutions, or languages?

Theme 3: Institutional and System Outcomes

- 7. Have you observed any institutional changes or improvements in biosafety and biosecurity practices resulting from the training programs?
- 8. How did the training support broader institutional or regional goals related to biosafety and biosecurity?

Theme 4: Sustainability and Support Mechanisms

- 9. After the trainings, were there structured follow-up mechanisms (e.g., mentorship, refresher courses, technical support)?
- 10. What challenges did you encounter in maintaining trainee motivation and skill application after the training?
- 11. In your opinion, what could have strengthened the sustainability of training outcomes?

Theme 5: Lessons Learned and Recommendations

- 12. From your experience, what were the key strengths of the training program?
- 13. What were the main challenges faced during the design, delivery, or post-training phases?
- 14. What two or three major improvements would you recommend for future biosafety and biosecurity capacity-building programs across Africa?

C. IDI Guide Trainees

Theme 1: Training Experience and Skills Gained

- Can you describe the training you received under the BSBS program?
- What specific skills or knowledge did you gain through the training?

Theme 2: Application of Skills

- Since the training, have you had opportunities to apply the skills in your work?
- Can you give one or two examples of a time when the training helped you improve safety or practices in your lab/institution?

Theme 3: Outcomes and Changes

- Have you noticed any changes in how biosafety and biosecurity are handled at your institution after the training?
- Are you more confident or better supported in your biosafety-related work now?

Theme 4: Sustainability and Future Needs

- After the training, have you received any support (mentorship, resources, follow-up workshops) to keep improving your biosafety/biosecurity work?
- What additional training or support would help you be even more effective?

Theme 5: Lessons Learned and Recommendations

- What did you like most about the training program?
- What improvements would you suggest for future biosafety and biosecurity training programs?

D. IDI Guide Laboratory Technician

Theme 1: Strategic Implementation

- Can you describe your institution's role in implementing the BSBS Strategic Plan?
- What were the main interventions or initiatives you were involved in?

Theme 2: Capacity Strengthening and Institutional Change

- Have you seen any improvements in how your lab works or is managed over the past five years?
- What contributed to those changes? What gaps remain?
- Did you or your colleagues receive any biosafety or biosecurity training?
- Were there any improvements in equipment, SOPs, or lab protocols?

Have risk assessment or waste disposal procedures changed?

Theme 3: Regional Coordination and Collaboration

- How has regional coordination (through Technical Working Groups, etc.) supported your work?
- What have been the successes and challenges of cross-country collaboration?

Theme 4: Impact and Outcomes

- What have been the most significant results or outcomes from the BSBS strategy?
- How have these outcomes affected public health or institutional practices?

Theme 5: Sustainability and Ownership

- Are the activities or changes introduced by the BSBS strategy likely to continue without external support?
- What mechanisms are in place to ensure sustainability?

Theme 6: Lessons Learned and Future Directions

- What key lessons have emerged during the implementation of the strategy?
- What would you recommend for the next strategic plan?

E. IDI guide Implementor

1. Strategic Implementation

Has your institution adopted or used the regulatory and certification framework for biosafety and biosecurity?

What key activities did you undertake to comply with the established minimum standards?

2. Standards and Compliance

Were the standards practical to apply at your facility?

To what extent did you align your practices with international or regional benchmarks?

3. Assessments and Feedback

Did your institution undergo an assessment using the standard checklist?

What were the key findings, and how did you respond to them?

4. Certification and Recognition

Has your institution received certification (e.g., Level 1-4 or Star 0-5)?

What did that certification involve and how was it recognized institutionally or nationally?

5. Training and Institutional Support

Were staff trained on the minimum biosafety and biosecurity standards?

How did this training affect your institution's readiness or performance?

6. Sustainability and Monitoring

How are improvements maintained after assessment?

Are there internal mechanisms to ensure continued compliance with standards?

7. Lessons and Recommendations

What lessons have you learned from implementing the regulatory and certification standards?

What should be prioritized or improved in the next 5-year strategy?

F. IDI guide Assessor

1. Strategic Framework Development

Were you involved in or consulted during the development of the regulatory and certification framework for high containment facilities?

To what extent has the framework been adopted or adapted nationally?

2. Standards and Benchmarks

Are the biosafety and biosecurity standards you assess aligned with international guidance (e.g., WHO, OIE, FAO)?

How practical and realistic are the regional benchmarks for national-level implementation?

3. Assessment Tools and Methodology

Were you trained to use standardized assessment tools or checklists for high containment facilities?

How consistently are these tools used across different institutions or countries?

4. Certification System

Has the tiered certification model (e.g., level 1-4 or star 0-5) been implemented in your assessments?

How do you determine which level or star rating a facility receives?

5. Training and Capacity Building

Did you receive training through an Africa CDC Regional Centre of Excellence?

How effective was this training in preparing you to carry out credible assessments?

6. Feedback and Use of Results

Were assessment results shared with implementers and followed up on?

Were the recommendations typically implemented?

7. Lessons and Recommendations

What worked well in your experience as an assessor?

What improvements would you suggest for the assessment or certification system?

G. IDI guide Legal Mapping

Theme 1: Strategic Implementation

Can you describe your role in the legal mapping or development of biosafety and biosecurity legislation in your country?

What were the key milestones or activities undertaken under the BSBS Strategic Plan related to legal frameworks?

Theme 2: Capacity Strengthening and Institutional Change

Has the BSBS strategy contributed to strengthening national legal and regulatory capacity for biosafety and biosecurity?

Were there trainings or technical support provided for legal or policy formulation? What was the impact?

Theme 3: Regional Coordination and Collaboration

How did regional coordination (e.g., through Africa CDC, TWGs, or RCCs) support legal harmonization or domestication efforts?

Did you engage with counterparts from other countries on legal or policy issues? What worked well or was challenging?

Theme 4: Impact and Outcomes

What legal or regulatory changes have occurred in your country as a result of the BSBS Strategic Plan?

Have new biosafety or biosecurity laws, regulations, or policies been adopted, updated, or implemented?

Theme 5: Sustainability and Ownership

Are there national mechanisms or institutions in place to sustain legal and policy work initiated under the BSBS plan?

Is there political or institutional buy-in for continued legal reform in biosafety and biosecurity?

Theme 6: Lessons Learned and Future Directions

What lessons have you drawn from your experience contributing to legal mapping or framework development?

What would you recommend for the next 5-year strategy regarding legal and regulatory priorities?

Annex 6: Focus Group Discussion Guides

A Focus Group Discussion Guide (GENERIC)

This guide is intended to support Focus Group Discussions (FGDs) for the end-term evaluation of the BSBS 5-Year Strategic Plan (2021-2025). It includes an informed consent script, group facilitation tips, and thematic discussion questions aligned with the evaluation objectives.

In collaboration with several partners, Africa CDC held a series of consultative workshops to determine the status of biosafety and biosecurity capacity implementation continent wide and develop a set of regional priorities to address capacity gaps. Africa CDC developed a Five-Year Strategic Plan (2021-2025) to address these priority areas, using a regional approach. Africa CDC is leading end of BSBS 5-Year Strategic Plan (2021-2025) evaluation. The evaluation aims at determining the overall achievement of the BSBS Strategic Plan, identify lessons learned, challenges and make recommendations to inform the next 5-Year strategy.

Informed Consent

Hello, my name is [Your Name], and I'm working with Freda Loy, the Lead Evaluator for the data collection as per the Monitoring and Evaluation Framework. She may engage with you directly during the data collection. She is expected to gather and summarize information provided by different sources and develop Draft report that will be reviewed and validated at the Regional Consultative Meeting 27-28 May 2025 in Addis Ababa. We greatly appreciate your consideration and support with information required.

The purpose of this discussion is to hear your group's views on the implementation and effects of the BSBS Strategic Plan. Your responses will help assess progress, challenges, and lessons learned to inform the next strategy. This focus group discussion is expected to last approximately 60 to 90 minutes.

The duration allows for discussion across six key thematic areas, including roles and participation, institutional capacity, coordination, impact, sustainability, and lessons learned. Participants are encouraged to share their perspectives freely, and the facilitator will ensure that everyone has an opportunity to contribute.

Please inform the facilitator in advance if you need to step out or have time constraints so that adjustments can be made where possible. Participation is voluntary, and there are no right or wrong answers. You may choose not to respond to any question. We ask everyone to respect each other's views and keep what is said here confidential.

With your permission, we would like to record this discussion. It will only be used for analysis, and your names will not be included in the report.

Do you all agree to participate and allow recording of the discussion? (Verbal group confirmation is sufficient.)

Facilitation Tips

Encourage all participants to speak, but avoid letting one person dominate. Maintain neutrality — do not express agreement or disagreement. Use open-ended questions and follow-up probes.

Pay attention to group dynamics and non-verbal cues. Record the session with permission and take notes.

Thematic Discussion Questions

Theme 1: Participation and Role

- What role has your institution played in the BSBS Strategic Plan?
- How involved were you in the planning, implementation, or coordination of its activities?

Theme 2: Capacity and Competencies

- What changes in institutional or technical capacity have you observed since the strategy began?
- Have trainings or technical support influenced your work?

Theme 3: Coordination and Collaboration

- Has the BSBS strategy improved coordination between institutions or countries?
- What has been helpful or challenging in working together regionally?

Theme 4: Effectiveness and Impact

- Which activities under the BSBS strategy do you feel have had the most impact? Why?
- What has changed in terms of biosafety or biosecurity practice as a result?

Theme 5: Sustainability and Ownership

- Are the results of the BSBS strategy likely to be sustained?
- What could help ensure long-term impact and ownership of the changes introduced?

Theme 6: Lessons and Suggestions

- What key lessons have you learned during this period?
- What advice would you give for the next BSBS Strategic Plan?

B. Focus Group Discussion Guide Trainers

Theme 1: Participation and Role

- What role has your institution played in the BSBS Strategic Plan?
- How involved were you in the planning, implementation, or coordination of its activities?

Theme 2: Capacity and Competencies

- What changes in institutional or technical capacity have you observed since the strategy began?
- Have trainings or technical support influenced your work?
- As a trainer, how did the training content and delivery evolve during the strategy?

Theme 3: Coordination and Collaboration

- Has the BSBS strategy improved coordination between institutions or countries?
- What has been helpful or challenging in working together regionally?

Theme 4: Effectiveness and Impact

- Which activities under the BSBS strategy do you feel have had the most impact? Why?
- What has changed in terms of biosafety or biosecurity practice as a result?
- Did you receive feedback from participants on how they used the training in practice?

Theme 5: Sustainability and Ownership

- Are the results of the BSBS strategy likely to be sustained?
- What could help ensure long-term impact and ownership of the changes introduced?

Theme 6: Lessons and Suggestions

- What key lessons have you learned during this period?
- What advice would you give for the next BSBS Strategic Plan?
- What improvements would you recommend for future training approaches?

C. Focus Group Discussion Guide Trainees

Theme 1: Participation and Role

- What role has your institution played in the BSBS Strategic Plan?
- How involved were you in the planning, implementation, or coordination of its activities?

Theme 2: Capacity and Competencies

- -What specific skills did you gain from the training?
- -How confident do you feel applying these skills?
- -What changes in institutional or technical capacity have you observed since the strategy began?
- Have trainings or technical support influenced your work?

Theme 3: Coordination and Collaboration

- Has the BSBS strategy improved coordination between institutions or countries?
- What has been helpful or challenging in working together regionally?

Theme 4: Effectiveness and Impact

- Which activities under the BSBS strategy do you feel have had the most impact? Why?
- What has changed in terms of biosafety or biosecurity practice as a result?
- Have your daily practices in the lab or field changed?

Theme 5: Sustainability and Ownership

- Are the results of the BSBS strategy likely to be sustained?
- What could help ensure long-term impact and ownership of the changes introduced?
- Do you think you'll continue using what you learned in your work?

Theme 6: Lessons and Suggestions

- What key lessons have you learned during this period?
- What advice would you give for the next BSBS Strategic Plan?

D. Focus Group Discussion Guide Laboratory Technicians

Theme 1: Participation and Role

- What role has your institution played in the BSBS Strategic Plan?
- Were you involved in any trainings, lab audits, or biosafety activities?
- How involved were you in the planning, implementation, or coordination of its activities?

Theme 2: Capacity and Competencies

- What changes in institutional or technical capacity have you observed since the strategy began?
- Have you applied any of the biosafety procedures or skills you learned?
- Have trainings or technical support influenced your work?

Theme 3: Coordination and Collaboration

- Has the BSBS strategy improved coordination between institutions or countries?
- What has been helpful or challenging in working together regionally?

Theme 4: Effectiveness and Impact

- Which activities under the BSBS strategy do you feel have had the most impact? Why?
- What has changed in terms of biosafety or biosecurity practice as a result?
- What has changed in your daily lab work because of the Strategic Plan?

Theme 5: Sustainability and Ownership

- Are the results of the BSBS strategy likely to be sustained?
- Do you think these changes in your lab will continue in the future?
- What could help ensure long-term impact and ownership of the changes introduced?

Theme 6: Lessons and Suggestions

- What key lessons have you learned during this period?
- What advice would you give for the next BSBS Strategic Plan?

Annex 7: Survey Questionnaires

A. Survey Questionnaire (ENGLISH)

Project

Africa Centres for Disease Control and Prevention (Africa CDC) Biosafety and Biosecurity 5-Year (2021-2025) Strategic Plan End-Term Evaluation

In collaboration with several partners, Africa CDC held a series of consultative workshops to determine the status of biosafety and biosecurity (BSBS) capacity implementation continent wide and develop a set of regional priorities to address capacity gaps. Africa CDC developed a Five-Year Strategic Plan (2021-2025) to address these priority areas, using a regional approach. Africa CDC is leading end of BSBS 5-Year Strategic Plan (2021-2025) evaluation. The evaluation aims at determining the overall achievement of the BSBS Strategic Plan, identify lessons learned, challenges and make recommendations to inform the next 5-Year strategy. This questionnaire is designed to collect feedback from key stakeholders involved in or affected by the implementation of the BSBS 5-Year Strategic Plan (2021–2025).

Note: The questions are intended for self-administration and should take you about 10 minutes to complete. Thank you!

Section A: Respondent Information

Name (optional)

Which of the following best describes your primary institution or place of work?

Africa CDC Secretariat

Regional Coordinating Centre (RCC)

National Public Health Institute (NPHI)

National Reference Laboratory (NRL)

Ministry or Government Agency (e.g. Ministry of Health, Agriculture, Environment, etc.)

Academic or Research Institution

Development or Implementing Partner

National Security / Defense Agencies (e.g., Ministry of Defense, security agency, biodefense unit)

Civil Society / NGO (e.g., advocacy organizations, community groups, non-profit implementers)

Regulatory Authority / Oversight Body (e.g., biosafety/biosecurity regulators, national lab certification boards)

Private Sector / Industry (e.g., diagnostics, biotechnology, pharmaceutical, private labs) Other (please specify)

Are you currently a member of a Regional Biosafety and Biosecurity Technical Working Group (RBB-TWG)?

Yes

Nο

Not sure

Which African Union Member State are you based in?

Are you or your institution involved in any activities under the Africa CDC Biosafety and Biosecurity (BSBS) 5-Year Strategic Plan (2021-2025), for example participating in technical working groups, attending training sessions, contributing to roadmap development, or

implementing biosafety and biosecurity assessments or standards etc.?*

Yes, No, Not sure

If No

Thank you for your response. Since this survey is specifically intended for those involved in activities under the BSBS 5-Year Strategic Plan (2021–2025), no further questions are required. We appreciate your time.

If Not sure

Are you aware of the Africa CDC biosafety and biosecurity 5-Year Strategic Plan (2021–2025)?

Yes, No, I've heard of it, but I'm not familiar with the details

To your knowledge, has your institution been involved in any biosafety and biosecurity-related activities in recent years (e.g., training, assessments, or coordination)?

Yes, No, Not sure

In your opinion, how important is regional coordination in strengthening biosafety and biosecurity across Africa?

Not important at all

Slightly important

Moderately important

Very important

Extremely important

Would you like to be involved in future activities under the next biosafety and biosecurity Strategic Plan (2025–2030)?

Yes

No

Maybe

Section B: Capacity Building and Training

Have you received training on biosafety and biosecurity under the 5-year biosafety and biosecurity Strategic Plan (2021-2025)?*

Yes

No

If yes, how relevant was the training to your day-to-day work?

Not at all relevant

Slightly relevant

Moderately relevant

Mostly relevant

Very relevant

To what extent did the training under the 5-year Strategic Plan improve your knowledge and skills in biosafety and biosecurity?

Not at all

To a limited extent

To a moderate extent To a great extent To a very great extent

To what extent have you applied the knowledge and skills gained from the biosafety and biosecurity trainings under the 5-year BSBS Strategic Plan in your work?

Not at all To a limited extent To a moderate extent To a great extent Extensively

Please give one example of how you have applied the skills gained in your role or institution

Has the training under the 5-year BSBS Strategic Plan contributed to improved institutional practices?

Yes

No

Not sure

Following your participation in biosafety and biosecurity trainings under the (2021–2025) Strategic Plan, has your institution provided you with any tools, resources, or follow-up support to help apply what you learned?

Yes

No

Not sure

To what extent has your institution supported the application of biosafety and biosecurity knowledge and practices gained through these trainings?

Not at all

To a limited extent

To a moderate extent

To a great extent

Fully supported

Please describe the type of tools, resources, or follow-up support your institution provided (e.g., job aids, SOPs, mentorship, supervision, equipment, refresher sessions, etc.)

Section C: Coordination and Technical Support

Have you or your institution participated in Regional Biosafety and Biosecurity - Technical Working Group (RBB-TWG) meetings or activities?*

Yes

No

How useful have RBB-TWG engagements been in strengthening coordination?

Not useful

Slightly useful

Moderately useful Mostly useful Very useful

Has your institution received any technical support related to biosafety and biosecurity as part of the implementation of the BSBS 5-Year Strategic Plan (2021–2025)?*

Ves

No

Not sure

If yes, how timely and relevant was the support?

Not at all

To a limited extent

To a moderate extent

To a great extent

Very much

If yes, please specify the type of technical support received

Section D: Impact and Sustainability

To what extent has your institution adopted or aligned with the regional biosafety and biosecurity standards developed or promoted under the BSBS 5-Year Strategic Plan (2021–2025)?*

Not at all

To a limited extent

To a moderate extent

To a great extent

Completely

Are the improvements introduced under the biosafety and biosecurity Strategic Plan likely to be sustained in your institution?*

Very unlikely

Unlikely

Not sure/Neutral

Likely

Very likely

No improvements observed/ Not Applicable

What are the main factors that would support the sustainability of changes introduced under the Biosafety and Biosecurity Strategic Plan (2021–2025)?*

Section E: Reflections and Recommendations

What have been the main institutional or operational challenges in implementing the biosafety and biosecurity 5-year Strategic Plan (2021-2025) activities in your country or organization?*

What lessons or good practices would you share from the biosafety and biosecurity 5-year Strategic Plan (2021-2025) experience?*

What recommendations do you have for the next biosafety and biosecurity Strategic Plan (2025-2030)?*

Section F: Additional questions (Equity and Awareness)

In your opinion, were the biosafety and biosecurity activities implemented under the BSBS 5-Year Strategic Plan (2021–2025) inclusive of gender, One Health stakeholders, and representation across the five Africa CDC regions?*

Not at all inclusive Slightly inclusive Moderately inclusive Mostly inclusive Very inclusive

Are you aware of the African Union biosafety and biosecurity Legal Framework?*

Yes

No

Not sure

Have you or your institution been involved in any activities related to the development or implementation of your country's roadmap for domestication of the African Union BSBS Legal Framework?

Yes

No

Not sure

If Yes, please describe the type of involvement

Thank you for participating in this important evaluation. Your input is valuable and will contribute to shaping the next phase of Africa CDC's Biosafety and Biosecurity Strategic Plan (2025-2030).

B. Survey Questionnaire (FRENCH)

Projet

Évaluation à long terme du plan stratégique de fin de stratégie des Centres africains de contrôle et de prévention des maladies (Africa CDC)

En collaboration avec plusieurs partenaires, Africa CDC a organisé une série d'ateliers consultatifs pour déterminer l'état de la mise en œuvre des capacités de biosécurité et de bio sûreté (BSBS) à l'échelle du continent et élaborer un ensemble de priorités régionales pour combler les lacunes en matière de capacités. Africa CDC a élaboré un plan stratégique quinquennal (2021-2025) pour aborder ces domaines prioritaires, en utilisant une approche régionale. Il dirige l'évaluation de fin du plan stratégique quinquennal de BSBS (2021-2025). Cette dernière vise à déterminer la réalisation globale du plan stratégique de BSBS, à identifier les leçons apprises, les défis et à formuler des recommandations pour éclairer la prochaine stratégie quinquennale. Ce questionnaire est conçu pour recueillir le retour d'information (Observations) des principales parties prenantes impliquées ou affectées par la mise en œuvre du plan stratégique quinquennal BSBS (2021-2025).

Remarque : Les questions doivent être répondus par chaque intervenant et devraient vous prendre environ 10 minutes à remplir. Merci !

Section A : Renseignements sur le répondant

Nom (facultatif)

Lequel des énoncés suivants décrit le mieux votre établissement principal ou votre lieu de travail ?

Secrétariat de Africa CDC

Centre Régional de Coordination (CCR)

Institut National de Santé Publique (INSP)

Laboratoire National de Référence (LNR)

Ministère ou organisme gouvernemental (par exemple, ministère de la Santé, de l'Agriculture, de l'Environnement, etc.)

Établissement d'enseignement ou de recherche

Partenaire de développement ou de mise en œuvre

Organismes de sécurité nationale / défense (par exemple, ministère de la Défense, agence de sécurité, unité de bio défense)

Société civile / ONG (par exemple, organisations de défense des droits, groupes communautaires, organismes de mise en œuvre à but non lucratif)

Autorité de réglementation / Organisme de surveillance (p. ex., organismes de réglementation de la biosécurité et de la bio sûreté, conseils nationaux de certification des laboratoires)

Secteur privé/industrie (p. ex., diagnostics, biotechnologie, produits pharmaceutiques, laboratoires privés)

Autre (veuillez préciser)

Êtes-vous actuellement membre d'un groupe de travail technique régional sur la bio sûreté et la bio sûreté (GTB-RBB) ?

Oui

Non

Pas sûr

Dans quel État membre de l'Union africaine êtes-vous basé?

Êtes-vous impliqué(e) dans des activités dans le cadre du Plan stratégique quinquennal (2021-2025) des Africa CDC (2021-2025), par exemple en participant à des groupes de travail techniques, en assistant à des sessions de formation, en contribuant à l'élaboration d'une feuille de route, ou en mettant en œuvre des évaluations ou des normes de biosécurité et de bio sûreté, etc. *

Oui

Non

Pas sûr

Si Non

Merci pour votre réponse. Étant donné que cette enquête s'adresse spécifiquement aux personnes impliquées dans les activités du plan stratégique quinquennal de la BSBS (2021-2025), aucune autre question n'est requise. Nous vous remercions de votre temps.

Si vous n'êtes pas sûr

Connaissez-vous le Plan stratégique quinquennal de biosécurité et de bio sûreté de Africa CDC (2021-2025) ?

Oui

Non

J'en ai entendu parler, mais je ne connais pas les détails

À votre connaissance, votre établissement a-t-il participé à des activités liées à la biosécurité et à la bio sûreté au cours des dernières années (p. ex. formation, évaluations ou coordination)?

Oui

Non

Pas sûr

Selon vous, quelle est l'importance de la coordination régionale dans le renforcement de la biosécurité et de la biosureté en Afrique ?

Pas important du tout

Légèrement important

Moyennement important

Très important

Extrêmement important

Souhaitez-vous participer aux activités futures dans le cadre du prochain Plan stratégique de biosécurité et de bio sûreté (2025-2030) ?

Oui

Non

Peut-être

Section B : Renforcement des capacités et formation

Avez-vous reçu une formation sur la biosécurité et la bio sûreté dans le cadre du Plan stratégique quinquennal sur la biosécurité et la bio sûreté (2021-2025) ?*

Oui

Non

Si oui, dans quelle mesure la formation a-t-elle été pertinente pour votre travail quotidien ?

Pas du tout pertinent

Légèrement pertinent

Moyennement pertinent

Surtout pertinent

Très pertinent

Dans quelle mesure la formation dans le cadre du plan stratégique quinquennal a-t-elle amélioré vos connaissances et vos compétences en matière de biosécurité et de bio sûreté ?

Pas du tout

Dans une faible mesure

Dans une mesure modérée

Dans une grande mesure

Dans une très grande mesure

Dans quelle mesure avez-vous appliqué dans votre travail les connaissances et les compétences acquises lors des formations en biosécurité et en bio sûreté dans le cadre du plan stratégique quinquennal de la BSBS ?

Pas du tout

Dans une mesure limitée

Dans une mesure modérée

Dans une grande mesure

De manière extensive

Veuillez donner un exemple de la façon dont vous avez appliqué les compétences acquises dans votre rôle ou votre institution

La formation dans le cadre du plan stratégique quinquennal BSBS a-t-elle contribué à améliorer les pratiques institutionnelles ?

Oui

Non

Pas sûr

À la suite de votre participation à des formations en biosécurité et en bio sûreté dans le cadre du Plan stratégique (2021-2025), votre établissement vous a-t-il fourni des outils, des ressources ou un soutien de suivi pour vous aider à appliquer ce que vous avez appris ?

Oui

Non

Pas sûr

Dans quelle mesure votre établissement a-t-il soutenu l'application des connaissances et des pratiques en matière de biosécurité et de bio sûreté acquise dans le cadre de ces formations ?

Pas du tout

Dans une très faible mesure

Dans une certaine mesure

Dans une large mesure

Entièrement pris en charge

Veuillez décrire le type d'outils, de ressources ou de soutien de suivi que votre établissement a fournis (p. ex., outils de travail, SOPs, mentorat, supervision, équipement, séances de recyclage, etc.)

Section C : Coordination et appui technique

Avez-vous ou votre établissement participé aux réunions ou aux activités du Groupe de Travail Technique Régional sur la biosécurité et la bio sûreté (GTT-RBB) ?

Oui

Non

Dans quelle mesure les engagements du GTT RBB ont-ils été utiles pour renforcer la coordination ?

Inutile

Légèrement utile

Moyennement utile

Surtout utile

Très utile

Votre établissement a-t-il reçu un soutien technique lié à la biosécurité et à la bio sûreté dans le cadre de la mise en œuvre du plan stratégique quinquennal de la BSBS (2021-2025) ?*

Oui

Non

Pas sûr

Si oui, dans quelle mesure le soutien a-t-il été opportun et pertinent ?

Pas du tout

Dans une très faible mesure

Dans une mesure modérée

Dans une large mesure

Beaucoup

Dans l'affirmative, veuillez préciser le type d'assistance technique reçu

Section D: Impact et durabilité

Dans quelle mesure votre établissement a-t-il adopté ou harmonisé les normes régionales de biosécurité et de bio sûreté élaborées ou promues dans le cadre du plan stratégique quinquennal de la BSBS (2021-2025) ? *

Pas du tout

Dans une très faible mesure

Dans une mesure modérée

Dans une large mesure

Beaucoup

Les améliorations apportées dans le cadre du Plan stratégique de biosécurité et de bio sûreté sont-elles susceptibles d'être maintenues dans votre établissement ? *

Très peu probable

Improbable

Incertain/Neutre

Probable

Très probable

Aucune amélioration observée/ Non applicable

Quels sont les principaux facteurs qui soutiendraient la durabilité des changements introduits dans le cadre du Plan stratégique en matière de biosécurité et de bio sûreté (2021-2025) ? *

Section E: Réflexions et recommandations

Quels ont été les principaux défis institutionnels ou opérationnels dans la mise en œuvre des activités du Plan stratégique quinquennal de biosécurité et de bio sûreté (2021-2025) dans votre pays ou organisation ? *

Quelles leçons ou bonnes pratiques partageriez-vous de l'expérience du Plan stratégique quinquennal en matière de biosécurité et de bio sûreté (2021-2025) ? *

Quelles recommandations avez-vous pour le prochain Plan stratégique de biosécurité et de bio sûreté (2025-2030) ? *

Section F : Questions supplémentaires (équité et sensibilisation)

À votre avis, les activités de biosécurité et de bio sûreté mises en œuvre dans le cadre du plan stratégique quinquennal de la BSBS (2021-2025) ont-elles tenu compte du genre, des parties prenantes de l'approche « Une seule santé » et de la représentation dans les cinq régions africaines des CDC ?

Pas du tout inclus Légèrement inclusif Modérément inclusif Principalement inclus Très inclusif

Connaissez-vous le cadre juridique de l'Union africaine en matière de biosécurité et de bio sûreté ? *

Oui

Non

Pas sûr

Avez-vous ou votre institution été impliqué dans des activités liées à l'élaboration ou à la mise en œuvre de la feuille de route de votre pays pour la domestication du cadre juridique BSBS de l'Union africaine ?

Oui

Non

Pas sûr

Dans l'affirmative, veuillez décrire le type de participation

Je vous remercie de votre participation à cette importante évaluation. Votre contribution est précieuse et contribuera à façonner la prochaine phase du Plan stratégique de biosécurité et de biosécurité des CDC africains (2025-2030).

Annex 8: List of people interviewed

No	NAME	DESIGNATION	ORGANISATION COUNTRY		Interview Type
01	Dr. Talkmore Maruta	Director of Programs	African Society for Laboratory Medicine	Ethiopia	KII
02	Jaures Arnaud Noumedem	Biosafety and Biosecurity Technical Officer	Africa CDC Ethiopia		KII
03	Donewell Bangura	Epidemiologist / Laboratory Expert	Africa CDC	Ethiopia	KII
04	Dr. Yenew Kebede Tebeje	Acting Director Center for Lab Diagnostics and Systems	Africa CDC	Ethiopia	
05	Idosie Kenfack	Biosafety and Biosecurity Technical Officer	Africa CDC	Ethiopia	KII
06	Trevor Smith	Senior Program Manager	Global Affairs Canada	Canada	KII
	Nataly Spears		Global Affairs Canada	Canada	KII
	Tabitha Sabiiti		Global Affairs Canada	Canada	
07	Andrew Hebbeler	Director of Biosecurity	Coalition for Epidemic Preparedness Innovations	USA	KII
	Claire J. Standley	Senior Biosafety and Biosecurity Initiatives Lead	Coalition for Epidemic Preparedness Innovations USA		KII
08	Prof. Ciira Kiiyukia	Chairman	Examination and Examination Committee	nittee Kenya	
09	Zibusiso Masuku	Former Director	Southern RCoE, National Institute for Communicable Diseases	South Africa	KII
10	Abdourahmane Sow	Director	Western RCoE, The Institut Pasteur de Dakar	Senegal	KII
11	Jacob Lusekelo	EA RCOEBB Coordinator	Ministry of Health	United Republic of Tanzania	KII
12	Hayley Severance	Deputy Vice President	Nuclear Threat Initiative (NTI) Bio	USA	KII
	Gabby Essix	Senior Program Officer	Nuclear Threat Initiative (NTI) Bio	USA	KII
13	Mutesi Christine Fortunate Rebecca	Legal Officer	Africa CDC	Ethiopia	KII
14	Maureen Ellis	Executive Director	International Federation of Biosafety Associations Tanzania		KII
15	Ali Asy	Professor of Pharmacology	Animal Health Research Institute, Agriculture Egypt Research Center		KII
16	Larbi BAASSI Ph.D	Executive Assistant/ Biorisk management Adviser	National Institute of Hygiene, Ministry of Health Morocco		KII
17	Monier Sharif	Vice-chairman of the Libyan National Committee for Biosafety and Bioethics (LNCBB)	Libyan Academy for Postgraduate studies, Aljabal Libya) Alakhdar		KII

18	MOUINGA ONDEME Augustin Ghislain	PhD, Researcher	Interdisciplinary Centre for Medical Research of Gabon Franceville (CIRMF)		KII
19	Montserrat Kobe Elonga	Technicien de laboratoire et Responsable de la Biosécurité et Biosûreté, Président du GTT BSBS Afrique Centrale	Laboratoire de recherche de Baney Guinée Équatoriale		KII
20	SALABIACKOU Helgα	Biologiste	Direction départementale des soins et services de santé au Jouilou.		
21	NZENGUELE Hutch-l'herbier	Biological Risk Manager	Lambaréné Medical Research Center (CERMEL)	Lambaréné Medical Research Center (CERMEL) Gabon	
22	Dr. Nonera Jean Marie	Directeur des Laboratoires de Biologie Médicale	Medical Biology Laboratories	Burundi	KII
23	Dr. Mabusetsa Joseph Raporoto Makalo	Chair of Biosafety and Biosecurity TWG Lesotho and Senior Laboratory Scientist	Central Veterinary Laboratory Lesotho		KII
24	Vimbai Grace Mukondiwa	Quality Manager, Africa Region Subject Matter Expert in Biorisk Management	Central Veterinary Laboratory	Central Veterinary Laboratory Zimbabwe	
25	Musonda Mandona	Biosafety and Biosecurity Advisor	Ministry of Health	Zambia	KII
26	Maruping Kenosi Maruping	Chief Medical Scientific Officer	National Health Laboratory, Ministry of Health	Botswana	KII
27	João Albano Mabunda	Biosafety and Biosecurity Focal point/ Biomedical Scientist	Ministry of Defense-Armed Forces, Health Mozambique Department, General Staff		KII
28	Kennedy K. Yatich	Head, Biosafety and Biosecurity / Chair East Africa Regional Biosafety & Biosecurity Technical Working Group (EA-RBB-TWG)	National Public Health Laboratories Kenya		KII
29	Khalid M. Osman Mohamad	Director General	National Authority for the Prohibition of Chemical and Biological Weapons	Sudan	KII
	Abubaker Elfadil	Chemist, head of inspection and verification sectin in SNAPCW	National Authority for the Prohibition of Chemical Weapons	Sudan	KII
	Abdalla Ali	National Contact Point- BWC	National Authority for the Prohibition of Chemical and Biological Weapons	Sudan	KII
30	Joseph Nkodyo	National Coordinator	Biosafety and Biosecurity Program, Central Public Uganda Health Laboratories		KII
31	Tadjidine Youssouf	Physician, Biologist-Infectious Disease Specialist/Head of the Working Group on Biosafety and Biosecurity	National Laboratory of the CHN of Reference El Union of the Comoros Maarouf		KII
32	Tafesse Koran	Head, Biorisk Management Desk of Animal Health Institute	National Veterinary Reference Laboratory Ethiopia		KII
33	Ayni Muhiadin Mohamed	Biosafety and Biosecurity focal point	National Public health reference Laboratory, Minister of health	Somalia	KII

34	Aluel Adiang	Technical Trainer (Quality Assurance) and member of the advisory board	National Bureau of Standards South Sudan		KII
35	Anthony Ahumibe	Ex-Chair Western RBB-TWG, Senior Laboratory Technical Advisor	Nigeria Centre for Disease Control Nigeria		KII
36	Dr. Donald I. Ofili	Current chair, Western RBB-TWG; Director, MLSCN Accreditation Service	Medical Laboratory Science Council of Nigeria Nigeria		KII
37	Leidiza dos Santos Tavares	Laboratory Technician Biosafaty Responsable BRM Trainer	National Institute of Public Health Cape Verde		KII
38	Dr. Olivier Manigart	Senior Team Leader	PROALAB – Project for strengthening epidemiological surveillance through laboratory systems, West African Health Organization – GFA Consulting Group – Public Health School, Université Libre de Bruxelles, Belgium		KII
39	Ousman Sorie Conteh	Biosafety and Biosecurity Officer, and Laboratory Coordinator	Central Public Health Reference Laboratory (CPHRL) and National Aids Control Programme (NACP)		KII
40	Abdul Sesay	Head of the Genomic Strategic Core Platform at the unitMRC Unit,	National Public Health Lab Gambia		KII
41	Djibril SANGARE	Senior Scientist, Professor, USTTB/FMOS Researcher	MRTC laboratory Mali		KII
42	Charles Quaye, PhD	Safety Manager, NMIMR	Noguchi memorial Institute for Medical Research Ghana		KII
43	IGUER-MESBAH Fellα	Research Officer Head of the biosecurity unit, biosafety, hygiene and safety	Pasteur Institute of Algeria Algeria e		IDI
44	Abderrazak ELKHANTOUR	Virologist & Biosafety Officer	National Office of Food Safety and Sanitary Products	Morocco	IDI
45	Dr. Samira Senouci	Microbiologist pHD	Public Health Consultant and First Vice-President Morocco of Moroccan Biosafety Association		IDI
46	Dr. Leila Dahbia Leila ANES- BOULAHBAL	Head of Enterovirus Lab/ WHO expert	Institut Pasteur d'Algérie /OMS Algeria		IDI
47	Bokabela Balamba Blandin	Medical Biologist	University Clinics of Kinshasa Democratic Republic of Congo/DRC		IDI
48	Dr. NGUWOH Philippe Salomon	Head of Immunoserology Lab / Coordinator of NPHL Biosafety Committee	National Public Health Laboratory Cameroon		IDI
49	Ladislao Ekiri NGOMO MIKUE	Médecin, responsable du laboratoire de biologie moléculaire à Bata	Ministère de la santé	Equatorial Guinea	IDI

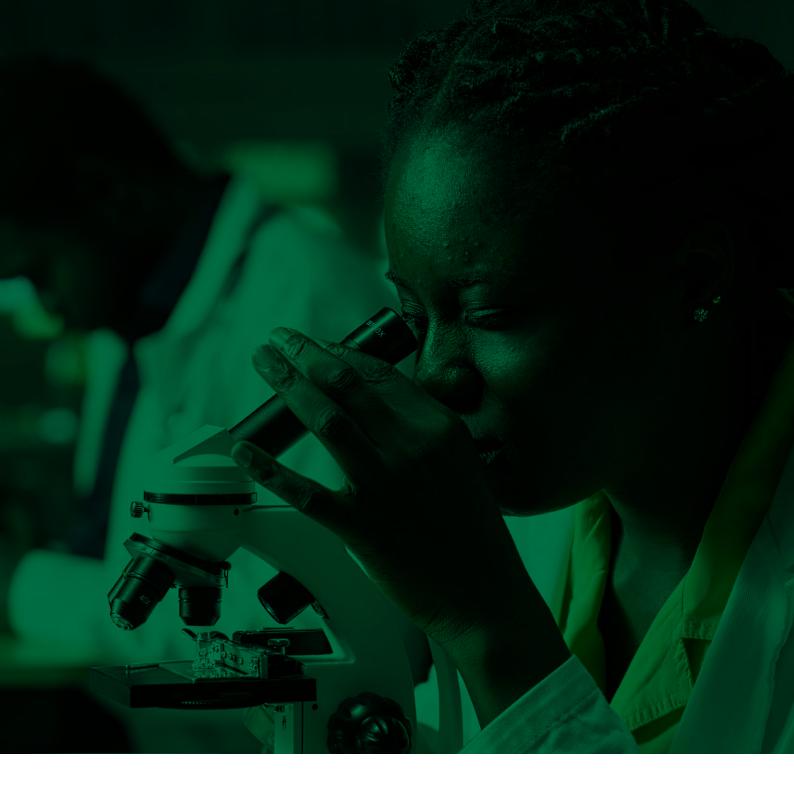
50	Patricia Mwale	Quality Officer/ Biomedical Scientist	University Teaching Hospitals-Adult Zambia Hospital,Pathology and Microbiology Department,Virology Laboratory		IDI
51	Mr. Derrick Themba Khumalo	Chairperson of National Biosafety and Biosecurity TWG	Eswatini Health Laboratory Services Eswatini		IDI
52	Dr. Patrick Maburu Masokwane	Director of Health Inspectorate	Botswana Ministry of Health Botswana		IDI
53	Donatus Mwambete	Lab scientist, Coordinator for Biosafety and Biosecurity	Ministry of Health	Tanzania	IDI
54	Rumbi Zain Dungwani	Subject Matter Expert for Biological Waste Management	RCoE	Kenya	IDI
55	RANDRIAMORA Nirharosoa de Borgia	Veterinary Inspector	National Veterinary Diagnostic Laboratory	Madagascar	IDI
56	Ngangali Jean Pierre	Highly Contagious diseases Specialist	Rwanda Biomedical Centre/ National Reference Laboratory	Rwanda	IDI
57	Dr. Stephen Balinandi	Principal Research Officer	Uganda Virus Research Institute	Uganda	IDI
58	SYLIDION KAGUNILA	Biosafety Cabinets and Biocontainment Certifier/Technical manager	CALLAB TANZANIA TANZANIA		IDI
59	Chala Dima Jalata	Researcher and Deputy Biosafety Officer	Animal Health Institute, MoA Ethiopia		IDI
60	Geofrey Jagero	President	Biorisk Management Association of Kenya	Kenya	IDI
61	Sandra Matinyi	Executive Director	Nuo Bioscience	Uganda	IDI
62	Dr Judith Chukwuebinim Okolo	Assistant Chief Research Officer/ Head of Incident Response Unit	National Biotechnology Research and Development Agency	Nigeria	IDI
63	El Hadji Abdourahmane FAYE	Responsable Biosécurité et Biosûreté de l'Institut Pasteur de Dakar et coordonnateur technique des formations au RCoEBB	Institut Pasteur de Dakar	SENEGAL	IDI
64	Mr. AARON T. MOMOLU	Deputy Director for Diagnostic Services, Internal QMS Auditor and Biorisk Management Trainer	National Public Health Reference Laboratory Liberia (NPHRL)/National Public Health Institute of Liberia (NPHIL)		IDI
65	Engnr Augustine Nzurumike	BSBS Assessor	ASLM Nigeria		IDI
66	DR. KILINDA IMANUEL KILEI	LEGAL CONSULTANT AND PUBLIC HEALTH SPECIALIST	UNIVERSITY OF SALFORD /INDEPENDENT UNITED KINGDOM/SIERRA LEONE		IDI
67	GUINA Denise Affoué Blassonny	Pharmacien Biologiste	Laboratoire National de Santé publique (LNSP) Côte d'Ivoire		IDI
68	Charles Quaye, PhD	Safety Manager, NMIMR	Noguchi memorial Institute for Medical Research	Ghana	IDI

69	TRAORE DIPOMIN FRANCOIS	ENSEIGNANT-CHERCHEUR	UNIVERSITÉ ALASSANE OUATTARA	CÔTE D'IVOIRE	IDI
70	Boubacar Mali Bah	Quality and Biosafety Manager	Regional Veterinary Laboratory of Labe	Guinea	IDI
71	Lamin Ndow	Senior Laboratory scientist & NPHL Biosafety officer	National public health laboratories, the Gambia	Gambia	IDI
72	Blessing Chibaya	Trainee	BSC Certification	Zimbabwe	FGD
73	Joseph Reason Khoza	Facility Officer - Head of the Engineering department, Trainee BCE	Agricultural Research Council, Onderstepoort Veterinary Institute, Transboundary Animal Diseases Campus	South Africa	FGD
74	Miss Vuyokazi Nongogo	Senior Scientist, Trainee, BWM	Protechnik Laboratories, a division of Armscor SOC Ltd	South Africa	FGD
75	IBRAHIMA HALILOU	Technical staff	Laboratoire National de Santé Publique	Cameroun	FGD
76	DIANE Abdoulaye	Research Engineer/Agent Responsible for Implementing SOPs	Franceville Interdisciplinary Center for Medical Research	Gabon	FGD
77	Fissou Henry YANDAI, PhD	Microbiologist, One Health Associate Researcher at the Livestock Research Institute for Development (IRED)	Ministry of Public Health and Prevention	Chad	FGD
78	MIAKOUKILA Noblesse Prestinα	Hospital biologist, Laboratory biosecurity manager	Ngoyo General Hospital	Republic of Congo	FGD
79	Fadzai Lambert	Subject Matter Expert		Zimbabwe	FGD
80	Gift Mulenga Chikoyi	Senior Environmental Health Officer, SME	Ministry of Health-HQ	Zambia	FGD
81	Nhlanhla Maluleke	Subject Matter Expert		South Africa	FGD
82	Elizabeth Nashidengo	Laboratory Technician, SME	Namibia University of Science and Technology	Namibia	FGD
83	Tembuso Nzalo	Environmental health officer, IPC officer, SME	Ministry of Health	Eswatini	FGD
84	Nthabiseng Senamolele	Subject Matter Expert		Lesotho	FGD
85	Khalid Fares	Professor, teacher researcher Chair of TWG North Africa	Cadi ayyad university Marrakech	Morocco	FGD
86	Dr. Ahmed Alien Mohammed Bachir	National laboratory director	Ministry of health	Sahrawi Republic	FGD
87	Hatem Fakhfakh	Professor of Genetics	Faculty of Sciences of Bizerte	Tunisia	FGD
88	Jihene HELLAL	Veterinary Biologist, Subject Matter Expert on Biorisk Management	Tunisian Veterinary Research Institute	Tunisia	FGD
89	Dayanne Stephanie Ernesta	Senior laboratory Technician	Seychelles Public Health Laboratory	Seychelles	FGD
90	Jacquit Edinho	Laboratory technician	Malagasy Medical Analysis Laboratory	Madagascar	FGD

91	QUENUM Rosine Olga	Biological Engineer	Viral Hemorrhagic Fevers Laboratory	Benin	FGD
92	Agom Danmarwa	Principal Veterinary Science Laboratory Technologist	National veterinary research institute Vom	Nigeria	FGD

Annex 9: Detailed Workplan

Phase	Key Activities	Timeline	Completion Date (2025)	Responsible person	Deliverable	Milestones
Preparation & Planning	Conduct an inception meeting with Africa CDC and ASLM Prepare and submit an inception report with clear methodology and reporting description	Week 1-2	16th April	Africa CDC, ASLM, Consultant	Finalised Inception report	Inception report approved
Data Collection	Desk Reviews, interviews, data gathering, preliminary analysis, surveys	Week 3-5	5th May	Consultant, Evaluation assistants	Cleaned data and Summary report	Data collection completed
Data Analysis & Draft Report	Data analysis, SWOT analysis, benchmarking & comparison, report drafting	Week 6-7	19th May	Consultant, Evaluation assistants	Draft 0 evaluation report	Draft submitted for review
Report validation	Stakeholder consultations, Present preliminary findings, revise based on feedback	Week 8-10	26th May	Africa CDC, ASLM, Consultant	Validation Meeting report	Validation meeting held
Final Report Drafting	Final report drafting, internal review	Week 11-13	30th June	Africa CDC, ASLM, Consultant	Final evaluation report	Final report submitted



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