

REGIONAL BIOSAFETY AND BIOSECURITY LEGAL FRAMEWORK

FOR THE AFRICAN UNION MEMBER STATES

2023



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EXECUTIVE SUMMARY

The World Health Organization (WHO) Joint External Evaluation conducted between 2016-2019, the Global Health Security Index (GHSI) and the regional consultations coordinated by Africa Centres for Disease Control and Prevention (Africa CDC), a specialized technical institution of the African Union (AU), highlighted biosafety and biosecurity capacity gaps among AU Member States. To address these gaps and assist Member States in building capacity to comply with international biosafety and biosecurity requirements and regulations, Africa CDC, Pan African Veterinary Vaccine Centre of the African Union (AU-PANVAC) and African Union – Interafrican Bureau for Animal Resources (AU-IBAR) in collaboration with AU Member States, and its Regional Collaborating Centres (RCC) launched the Regional Biosafety and Biosecurity Initiative (BBI). Key among its objective is to develop a regional biosafety and biosecurity legal framework (BSBS) that can be adopted and subsequently incorporated and domesticated in national legislation.

The BSBS legal framework shall provide guidance and underpin biosafety and biosecurity operations among AU Member States by elucidating how laboratories, institutions may handle high consequence pathogens. It will frame the manner in which training institutions and regulatory agencies could build stronger biosafety and biosecurity practices using a One Health inclusive of the human, animal, plant, and environmental sectors. It will define overarching technical requirements for those laboratories and institutions that manipulate and/or store High Consequence Agents and Toxins (HCAT). It will define the training standards for and capacity building requirements and specifications of biosafety and biosecurity professionals. Member States with a pre-existing legal architecture, should use this BSBS legal framework as benchmark to review the adequacy in scope and detail and update their legal arrangements accordingly. Where legal documents on biosafety and biosecurity do not exist, the Member States can adopt this BSBS legal framework to develop their national legislation.

The regional BSBS legal framework covers seven key areas refers to as domains of:

- (i) Domain 1: Requirement for the lead agency /institution responsible for regulating biosafety and biosecurity
- (ii) Domain 2: Development of national standards for biosafety and biosecurity
- (iii) Domain 3: Authority for biological risk assessment.
- (iv) Domain 4: Regulation of laboratory and facility requirements for handling HCATs

- (v) Domain 5: Education, training, and human resource development for all personnel who possess, use, manipulate, store, transfer or destroy/incinerate HCATs
- (vi) Domain 6: Transfer, storage, and disposal of HCATs

The development of the BSBS legal framework followed a regional consultative process of AU Member States utilizing the established multi-sectorial and multi-expert Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWG) established in Central, Eastern, Northern, Southern and West Africa. These RBB-TWG are coordinated by the Africa CDC Regional Collaborating Centres (RCCs) and guided by agreed upon Terms of Reference (ToRs). They have the mandate from Member States to coordinate and monitor implementation of the Regional Biosafety and Biosecurity Initiative. In addition, partners and other stakeholders were consulted individually and as part of the RBB-TWG to provide inputs including representatives from AU-IBAR, AU PANSAC, the World Health Organization (WHO), Food and Agriculture Organization (FAO), World Organization for Animal Health (OIE), International Federation of Biosafety Associations (IFBA), and in-country biosafety associations among others. The Specialized Technical Committees (STCs) for health, drug control and population and justice and legal affairs were consulted in which they endorsed and those committees adopted the BSBS legal framework.

Upon adoption, by AU Heads of States, the Africa CDC and its partners, will develop an implementation guidance document for the domestication and implementation of the legal BSBS framework by Member States. The document will provide a step-by-step guidance on how to use this BSBS legal framework, including other key steps of legal mapping, stakeholder engagement and training. The RBB-TWG shall advocate for and mobilize funds as well as monitor implementation of the BSBS legal framework requirements.

ACKNOWLEDGEMENTS

The BSBS legal Framework prepared by the Africa CDC, AU PANVAC and AU IBAR in collaboration with the African Union (AU) Member States and in partnership with its regional and international partners. Consultations with Member States were completed through the Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWG) and were coordinated by the Africa CDC secretariat and its RCCs.

The Africa CDC is grateful to all the AU Member States who participated in the consultative meetings through their respective RBB-TWG of Central, Eastern, Northern, Southern and West Africa. Africa CDC further acknowledges the respective RCCs, which hosted each of the regional consultative meetings.

Africa CDC is grateful to the following organizations that constituted the Expert Group and those members who conducted the initial research and developed first draft 0 framework, coordinated consultation meetings and compiled feedback received and edited the document and provided other support services.

- United States Centres for Disease Control and Prevention (US CDC)
- United States Defense Threat Reduction Agency (DTRA)

The following organizations reviewed and provided constructive feedback to the document.

- The Nuclear Threat Initiative (NTI).
- Food and Agriculture Organization (FAO)
- International Federation of Biosafety Association (IFBA)
- United States Centres for Disease Control and Prevention (US CDC)
- United States Defense Threat Reduction Agency (DTRA)
- Verification Research, Training and Information Centre (VERTIC)
- World Health Organization (WHO)
- World Organization for Animal Health (OIE)
- Biological Weapons Convention, Implementation Support Unit, UNODA

Africa CDC would like to express its great appreciation s to the African Society for Laboratory Medicine (ASLM) and Global Affairs Canada Weapons Threat Reduction Program for providing the resources to support the process of developing the framework.

ACRONYMS

Africa CDC	Africa Centres for Disease Control and Prevention
ASLM	Africa Society for Laboratory Medicine
AU	African Union
AU-IBAR	Pan African Veterinary Vaccine Centre of the African Union
AU-PANVAC	Pan African Veterinary Vaccine Centre of the African Union
BBI	Biosafety and Biosecurity Initiative
BSBS	Biosafety and Biosecurity
BWC	Biological Weapons Convention
FAO	Food and Agriculture Organization
HCAT	High Consequence Agents and Toxins
IHR	International Health Regulations
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
JEE	Joint External Evaluations
OIE	World Organization for Animal Health
RBB-TWG	Regional Biosafety and Biosecurity Technical Working Group
RCC	Regional Collaborating Centre
TOR	Terms of Reference
UNSCR	United Nations Security Council Resolution
WHA	World Health Assembly
WHO	World Health Organization

TERMS AND DEFINITIONS

The following terms and definitions are noted for the purposes of this document.

Accreditation – Written confirmation that an organization had demonstrated the competency to perform specified tasks. The tasks are performed following set standards. In the case of this BSBS framework, accreditation is conferred by an organization recognized by the International Laboratory Accreditation Cooperation (ILAC)¹

Agent – An infectious agent which can be a microorganism, like virus, bacteria, fungi, or other toxins either naturally occurring or genetically modified and have the potential to cause infection, allergy, toxicity to humans, animals, or plants.

Biosafety - Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release².

Biosecurity - Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion, or release³.

Certification - Written confirmation that a person, product, or process conforms to specified requirements and standards. In this BSBS framework, certification can be conferred by any institution recognized by the country to offer certification.

Designated agency/institution – An agency/institution

with fiscal, legal and administrative capability to oversee implementation of the requirements of the biosafety and biosecurity requirements in the country.

Domain: A major category of the law

Exposure - a situation or condition that makes someone likely to be harmed, especially when the person has not been protected from a hazard

¹ International Laboratory Accreditation Cooperation (ILAC). <https://ilac.org/>

² World Health Organization. Laboratory biosafety manual, 4th edition.
<https://www.who.int/publications/i/item/9789240011311>

³ World Health Organization. Laboratory biosafety manual, 4th edition.
<https://www.who.int/publications/i/item/9789240011311>

Hazard - A potential source of harm i.e. a condition, situation or an act with the potential to cause harm, injury or generating a public health emergency⁴.

High Consequence Agents and Toxins - These are biological agents and toxins that have been determined to have the potential to pose a severe threat to both human, animal, and plant health.

Legal Framework – Documents of the general rules, obligations and principles that with which must be complied .

Legal instrument - Legal documents that are agreed to by national or sub-national levels of government, the type of which vary by Member State's legal system.

Legal mapping- Determination of what laws exist, collect the information needed to analyze what those laws say, and ultimately measure the effect these laws have on health outcomes.

License - Legal authority granted to an individual to practice a profession within a designated scope of practice.

One Health approach: An approach to address a health threat at the human–animal–environment interface based on collaboration, communication and coordination across all relevant sectors and disciplines, with the ultimate goal of achieving optimal health outcomes for people, animals, and plants living in a shared environment; a One Health approach is applicable at the sub-national, national, regional and global level.

Pathogen - A microorganism that causes, or can cause, disease in human, animals or plants

Risk - A combination of the likelihood of the occurrence and magnitude of an adverse event or effect to animal, human environment and plant health.

Risk assessment - A systematic process for gathering, assessing and documenting information to assign a level of risk.

Toxin - A poisonous substance produced or derived from living plants, animals, or microorganism.

⁴ ISO 15190: 2020. Medical laboratories — Requirements for safety. <https://www.iso.org/standard/72191.html>

INTRODUCTION

Biosafety is concerned with the safety of humans, animals, plants and the environment from unintentional release of harmful biological agents and toxins whereas biosecurity is concerned with the protection, control of and accountability for biological materials and information related to these material and dual-use research. Accordingly, biosafety involves the containment principles, technologies and practices that are implemented to prevent their unintentional exposure. Biosecurity involves principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity guards against unauthorized access, loss, theft, misuse, diversion or release of biological agents and toxins.

The WHO Joint External Evaluations (JEE) and Global Health Security Index (GHSI) both demonstrated poorly developed biosafety and biosecurity capacities among the African Union (AU) Member States. In 2018, the World Organization for Animal Health (OIE) in collaboration with Global Affairs Canada organized a meeting where poor biological risk management and quality assurance in veterinary laboratories were identified with a multidisciplinary, multi-sectoral, and collaborative approach based solution proposed. In May 2019, supported by its regional and global partners, the Africa CDC launched the **Biosafety and Biosecurity Initiative** (BBI) aimed at strengthening the biosafety and biosecurity systems of AU Member States in order build their capacity to comply with international requirements and regulations such as the International Health Regulations (IHR) (2005), the Biological Weapons Convention (BWC), and United Nations Security Council Resolution (UNSCR) 1540⁵. The BBI was motivated by the recognition that the risk of a catastrophic biological event continues to be magnified by global travel, urbanization, terrorist nefarious interest in weapons of mass destruction, and rapid advances in biotechnologies that have the potential for misuse. These risks are the more contemporary - some resulting from technological innovation - additions to a long natural risk history of infectious disease outbreaks with devastating epidemic or pandemic potential.

Among the BBI's key objectives is the development of a **Biosafety and Biosecurity Legal Framework for the Africa Region**, which Member States can adapt and adopt to formulate country-specific legislation in support of national biosafety and biosecurity program. The BSBS framework allows for the

⁵ Africa CDC. Biosafety and Biosecurity Initiative. <https://africacdc.org/programme/laboratory-systems-and-networks/biosafety-and-biosecurity/>

establishment of (or mandating an existing) of an agency to administer and enforce biosafety and biosecurity oversight systems. The provisions of this e BSBS legal framework may be incorporated and adopted into national legal instruments for biosafety and biosecurity.

In order to advance and coordinate the implementation of the BBI in an inclusive and consultative manner within the African continent, five multi-sectoral **Regional Biosafety and Biosecurity Technical Working Groups** (RBB-TWG) made up of experts from the AU Member States, were established. These RBB-TWGs, guided by agreed upon Terms of Reference (ToR), were convened by the Africa CDC secretariat and its RCCs and will oversee the implementation of the BBI in all the five (5) Africa Union/Africa CDC regions of continent i.e. Eastern, Central, Northern, Southern, and Western Africa. The RBB-TWGs were additionally tasked with the development and review of this legal BSBS framework.

This **Biosafety and Biosecurity Legal Framework** is based on regional and international requirements for biosafety and biosecurity derived from:

- The International Health Regulations (IHR) (2005)⁶
- The World Health Assembly Resolution WHA 58.29 Enhancement of laboratory biosafety⁷
- The Cartagena Protocol on Biosafety to the Convention on Biological Diversity⁸
- The World Organization for Animal Health (OIE) Terrestrial Animal Health Code⁹
- The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals¹⁰
- The Biological Weapons Convention¹¹
- The United Nations Security Council Resolution 1540¹²

⁶ World Health Organization. International Health Regulations (2005) Third Edition.
<https://www.who.int/publications/i/item/9789241580496>

⁷ World Health Organization. The World Health Assembly Resolution WHA 58.29 Enhancement of laboratory biosafety. https://apps.who.int/iris/bitstream/handle/10665/20379/WHA58_29-en.pdf?sequence=1&isAllowed=y

⁸ United Nations. Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. https://treaties.un.org/doc/Treaties/2010/12/20101215%2005-26%20PM/Ch_27_8_c.pdf

⁹ World Organization for Animal Health. Terrestrial Animal Health Code.
<https://www.oie.int/standard-setting/terrestrial-code/access-online/>

¹⁰ World Health Organization for animal Health. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. <https://www.oie.int/standard-setting/terrestrial-manual/access-online/>

¹¹ United nations. Biological Weapons Convention. <https://www.un.org/disarmament/biological-weapons/>

¹² United nations. United Nations Security Council resolution 1540.
<https://www.un.org/disarmament/wmd/sc1540/>

- The OIE Biological Threat Reduction Strategy¹³
- World Health Organization. Laboratory biosafety manual, 4th edition¹⁴
- ISO 35001:2019; Biorisk management for laboratories and other related organizations, International Organization for Standardization, Geneva, 2019¹⁵
- The Nagoya Protocol on Access and Benefit-sharing¹⁶
- WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories- A Step Approach¹⁷

RATIONALE FOR DEVELOPING THE LEGAL BSBS FRAMEWORK

The WHO Joint External Evaluations (JEE) conducted among 44 AU Member States between 2016 and 2019 indicated that limited capacity on biosafety and biosecurity exists in Member States¹⁸. In addition, the regional consultative workshops coordinated by the Africa CDC through its five (5) RCCs, highlighted lack of or inadequate and fragmented legislation, regulations, and policy frameworks relevant to having effective biosafety and biosecurity systems. Member States further highlighted a number of key challenges to implementation such as lack of the translation of legal requirements into practice, having inadequate resources to support legislative framework requirements, lack of coordination between all relevant stakeholders, and lack of support from policy makers.

To address these challenges and assist Member States in building biosafety and biosecurity capabilities to comply with international requirements and regulations, Africa CDC, in collaboration with Member States, RCCs, and regional and international partners, developed this BSBS legal framework.

¹³ World Health Organization for Animal Health. <https://www.oie.int/scientific-expertise/biological-threat-reduction/>

¹⁴ World Health Organization. Laboratory biosafety manual, 4th edition. <https://www.who.int/publications/i/item/9789240011311>

¹⁵ International Organization for Standardization. ISO 35001:2019. Biorisk management for laboratories and other related organizations. <https://www.iso.org/standard/71293.html>

¹⁶ Convention on Biological Diversity. The Nagoya Protocol on Access and Benefit-sharing. <https://www.cbd.int/abs/>

¹⁷ World health Organization. WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories- A Step Approach. 2020. <https://apps.who.int/iris/bitstream/handle/10665/332244/9789241516266-eng.pdf?sequence=1&isAllowed=y>.

¹⁸ World Health Organization. Joint External evaluation mission reports. <https://www.who.int/ihr/procedures/mission-reports-africa/en/>

AFRICA CDC'S ROLE IN DEVELOPING THE BSBS FRAMEWORK

Taking into account the health challenges faced by the African continent and the necessity for an accountability framework for health security to protect citizens of the continent, the African Union Heads of States and Governments approved the establishment of the Africa Centres for Disease Control and Prevention (Africa CDC) through Assembly decision **AU/DEC.589 (XXVI)** at the African Union summit in January 2015 at Addis Ababa, Ethiopia. At its 26th ordinary session in January 2016, the assembly adopted the statute of the Africa CDC and its framework of operations. Africa CDC was officially launched on 31 January 2017¹⁹. Article 3(6) of the Africa CDC statute states that *“Africa CDC shall promote partnerships and collaborations among Member States to address the emerging and endemic diseases and public health emergencies”*. Article 5 of the statute also emphasized that *“Africa CDC shall work with the World Health Organisation (WHO) and other multisectoral partners and external partners as well as the Africa CDC Regional Collaborating Centres (RCCs) to pursue the strategic objectives of the Centre”*.

As the technical agencies of the African Union, Africa CDC, AU PANVAC, AU IBAR are committed to ensuring that the AU Member States have a comprehensive and strong legal foundation for biosafety and biosecurity that will promote and support the development of effective biosafety and biosecurity programs and practices and support overall capacity development of public health institutions in Member States.

RATIONALE OF THE LEGAL BSBS FRAMEWORK AT MEMBER STATES LEVEL

Following the review, adoption and endorsement the AU Specialized Technical Committees (STCs) on Health, Population and Drug Control and Justice and Legal Affairs, the Committee of Permanent Representatives, the Executive Council and the Heads of States, the BSBS legal framework will be presented for ratification by legislature of the Member State. At the Member State level, this BSBS legal framework, once ratified, shall become a recognized legal document for developing and enhancing biosafety and biosecurity systems and practices on the continent and on a country-specific implementation and improvement at the national level. This BSBS legal framework will underpin the operations of biosafety and biosecurity system within the country including how laboratories and institutions handle HCATs and how training institutions and regulatory agencies implement and

¹⁹ African Union. ASSEMBLY OF THE UNION Twenty-Sixth Ordinary Session 30 - 31 January 2016 Addis Ababa, ETHIOPIA. https://au.int/sites/default/files/decisions/29514-assembly_au_dec_588_-_604_xxvi_e.pdf

strengthen biosafety and biosecurity systems in the human, animal, plant, environmental, and biotechnology laboratories. It also stipulates the overarching technical requirements for laboratories and institutions manipulating and/or storing HCATs) and elaborates standards for training and capacity building for biosafety and biosecurity professionals.

A seven-step process is recommended by WHO on developing and implementing a comprehensive regulatory system for biosafety and biosecurity;²⁰

Step 1: Mobilize national commitment and resources for the development and implementation of a national biosafety and biosecurity policy.

Step 2: Conduct a national evaluation and surveys.

Step 3: Establish national institutions and operational mechanisms and develop best-fitting regulations

Step 4: Strengthen expertise to support implementation of a suitable regulatory system.

Step 5: Implement and enforce regulations.

Step 6: Establish national information exchange networks and international partnerships, and

Step 7: Review performance and adaptability to the national context and evolving risks.

A process of legal mapping will assist Member States to fully understand current legal authorities as they exist and plan for ways to revise or amend the instruments they have to address identified gaps and formally establish comprehensive biosafety and biosecurity legal instruments at the national, district, and or local level depending on the country context.

The BSBS legal framework shall designate a regulatory administrative and agency/institution with the responsibility for the evaluation, management, monitoring and implementation of biosafety and biosecurity systems and incident investigation of catastrophic events. This will ensure better coordination of all stakeholders concerned with biosafety and biosecurity by taking a One Health approach and including the human animal, plant, and environmental health sectors; security; customs; immigration; institutions of higher learning; legislature; civil society; and biosafety and biosecurity associations, among others. The BSBS framework emphasizes the importance of multisectoral

²⁰ WHO GUIDANCE on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories- a stepwise approach.
<https://apps.who.int/iris/bitstream/handle/10665/332244/9789241516266-eng.pdf?sequence=1&isAllowed=y>

coordination, and promotes clarity on roles, responsibilities, and given authorities as well as reduces duplication of efforts or any conflict of law.

APPLICATION OF THE BIOSAFETY AND BIOSECURITY LEGAL FRAMEWORK

This BSBS legal framework developed by Africa CDC, AU PANVAC, AU IBAR in collaboration with AU Member States and its regional and global partners can be applied in several ways including:

- *Where legislative instruments for biosafety and biosecurity already exists*, this BSBS legal framework may be used to review the Member State's existing legal instruments to ascertain their scope in terms of coverage and adequacy. Existing legal instruments can include the elements of seven (7) biosafety and biosecurity domains listed in this BSBS legal framework. To ensure a coordinated approach, the biosafety and biosecurity legal instruments at national level shall follow a system whereby a designated agency administers the biosafety and biosecurity regime described in this legal framework.
- *Where no biosafety and biosecurity legal instruments exists* at the national level, Member State can adopt or develop national legal instruments for biosafety and biosecurity, which should be in line with this BSBS legal framework to address national needs.

In both situations, this BSBS legal framework will assist Member States to better understand their existing legal capacity to support biosafety and biosecurity. Member States can follow the WHO stepwise approach to implementing regulatory requirements for biosafety and biosecurity.²¹

Through the Africa Union Biosafety and Biosecurity Taskforce made up of the technical agencies of Africa CDC, AU PANVAC and AU IBAR will work jointly to assist Member States in the implementation of the framework at national level using their specialized expertise in human and animal health. This One Health approach will ensure coordinated adoption and or adaption of the framework and development of appropriate national legislation that address requirements of this framework.

²¹ WHO GUIDANCE on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories- a stepwise approach.
<https://apps.who.int/iris/bitstream/handle/10665/332244/9789241516266-eng.pdf?sequence=1&isAllowed=y>

ORGANIZATION OF THE BIOSAFETY AND BIOSECURITY LEGAL FRAMEWORK

This BSBS legal framework is organized into six (6) domains (Figure 1). These domains are the key areas to be addressed in the laws, decrees, or regulations that influence biosafety and biosecurity activities. Each domain is made up of a list of attributes that characterize the domains. For example, a domain that establishes a national biosafety and biosecurity oversight body might have attributes describing the membership of the oversight body. Each attribute provides more detail about how legal instruments might include provisions to address an important aspect of the domain. A sub-attribute then provides a detail about how legal instruments might address an important aspect of its corresponding attribute. Each attribute and sub-attribute can be reviewed to consider what current legal authorities provide to support the biosafety and biosecurity activities relevant to that domain. The domains are:

1. Authorization of the establishment of a lead entity/agency responsible for regulating and managing biosafety and biosecurity systems
2. Development of national standards for biosafety and biosecurity
3. Authority for biological risk assessment
4. Regulation of laboratory and facility requirements for handling HCATs.
5. Education, training, and human resource development for all personnel who possess, use, manipulate, store, transfer or destroy/incinerate HCATs
6. Transfer, storage, and disposal of HCATs

Domain 1	
Legal domain corresponds to the major categories of law	Authority for biological risk assessment
Attributes provide more details about what could be covered in the legal instrument	3.2 Authorizes requires biological risk evaluation of agents and toxins for purposes of generating a national HCAT list. This includes:
Sub- Attributes provide additional specificity on characteristics to be covered	3.2.1 Creating Legal instrument includes a list of prohibited toxins, biological agents, and agents of concern (regulated but not prohibited) as an appendix 3.2.2 Reviewing and updating of the HCAT list every 2-3 years or whenever there are updates from research, science, or emergency of new risks

Fig. 1: Understanding how to review domains, attributes, and sub-attributes.

There is one additional section of this BSBS framework that address the following areas:

- Anticipated challenges and proposed solutions

HOW TO READ THE BIOSAFETY AND BIOSECURITY LEGAL FRAMEWORK

In this document, biosafety and biosecurity (BSBS) legal framework refers to this document to be used as a tool for development of national legislative instruments. This BSBS legal framework describes the legal instruments that can be used to support, to the extent that it does not exist, the introduction and maintenance of robust biosafety and biosecurity systems in AU Member States. Given that each Member States does not have the same or similar legal systems, this BSBS framework may contain some elements that may not be relevant or appropriate to some Member States. Some Member States are federations and others unitary states, which may or may not raise jurisdictional issues that must be resolved by the Member States themselves. By design, it cannot have and therefore lacks local detail. It cannot be prescriptive as Member States as sovereign entities will do what is appropriate for them. This BSBS legal framework is therefore conceived as a tool that Member States can use to draft national laws specific to their countries' threat environment. Finally, this BSBS legal framework describes anticipated challenges and propose solutions to problems countries may encounter in the process of developing, reviewing and implementing biosafety and biosecurity legal systems.

THE BIOSAFETY AND BIOSECURITY LEGAL FRAMEWORK

This section describes the seven legal domains to consider in BSBS legal framework.

DOMAIN 1: AUTHORIZATION OF THE ESTABLISHMENT OF AN AGENCY/INSTITUTION RESPONSIBLE FOR REGULATING AND MANAGING BIOSAFETY AND BIOSECURITY SYSTEMS

1. The BSBS legal framework authorizes the establishment of an agency/institution responsible for regulating and managing biosafety and biosecurity systems.

To ensure adherence to/compliance with biosafety and biosecurity norms and standards, there shall be clear assignment of the responsibility for the establishment, implementation, monitoring and management of national biosafety and biosecurity systems and incident-investigation of catastrophic events at the national level. The national agency/institution assigned this responsibility shall provide overarching national regulatory administration and coordination authority between all relevant agencies, institutions, and stakeholders that have biosafety and biosecurity functions. The agency/institution regulatory role shall include overseeing creation of legal instruments and the establishment of legally constituted authorities using a One Health, whole-of-government approach and in the design of the national biosafety and biosecurity management program.

The designated agency/institution shall work with and in collaboration with existing national structures. Its placement within national structures is overarching, providing overall oversight of implementation and compliance to biosafety and biosecurity requirements as stipulated in national legislations. This should resolve any existing administrative fragmentation of the management of biosafety and biosecurity systems, to the extent that they exist, across sectors, departments and agencies.

The designated agency can be:

- An agency/institution reporting directly to government
- Autonomous or semi-autonomous i.e. operate at arm's length independently with its own board, management and organization structure still accountable and reporting directly to government
- Funded by a protected public sector budget allocation directly or through the line ministry/department it falls under.
- Legally entitles to receive funds directly from external sources and be accountable to government on the use of all funds received from all sources.

The BSBS legal framework authorizes the establishment of an agency/institution responsible for regulating, managing and coordinating biosafety and biosecurity at a national level. The BSBS legal framework specifies the terms of reference of the agency/institution. The terms of reference shall stipulate the following:

- 1.1 The objectives, functions and activities of the agency/institution.
- 1.2 Development of strategic, business and staffing plans for the agency/institution
 - 1.2.1 There shall be stipulation of how the agency/institution administers, enforces, coordinates and monitors the implementation of biosafety and biosecurity requirements and to investigate the causes, consequences and remedial actions to be taken in response to catastrophic biological events in collaboration with other government entities/ministry/departments
- 1.3 Regulation of the identification and management of the HCATs. There shall be clear stipulation for:
 - 1.3.1 The requirement for development and maintenance of the core capacities for surveillance, assessment, and response to the threat of HCATs
 - 1.3.2 The identification of local capacity (laboratory/ies) to identify and confirm inventories all the HCATs. This shall include access to international laboratories.
 - 1.3.3 The mechanism and frequency of reviewing or revising list of HCATs
- 1.4 Development, regulation, updating and testing the national biosafety and biosecurity emergency response plan. This may include:
 - 1.4.1 Creation of multidisciplinary/multisectoral teams to rapidly respond to events that may constitute a public health emergency of international concern caused by the HCAT. The following shall be clearly defined;
 - 1.4.1.1 Frequency of testing the emergence response plans.
 - 1.4.1.2 Conditions for review and updating of emergence response plan including following testing of the plans, after a post review following an emergence, following a review and update of the HCAT list and emergency of new scientific knowledge.
- 1.5 Cooperation with relevant regional and international bodies during a Public Health Emergency of International Concern (PHEIC) and other preparedness activities. It must be clearly defined what constitutes a catastrophic biological event and the powers of investigation required to understand its causes, consequences and define the remedial actions to be taken.
- 1.6 Establishing and managing national systems that ensures there is prohibition of misuse of biological agents and toxins including the prohibition to develop, produce, stockpile or otherwise acquire, retain or use (i) biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes (ii) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.
- 1.7 Managing all matters pertaining to BWC implementation and to submit Confidence Building Measures to the BCW Implementation Support Unit.
- 1.8 Monitoring and managing internal oversight systems for Dual Use Research of Concern. This includes requiring research institutions to
 - 1.8.1 Conduct a risk assessment and develop a risk mitigation plan to ensure that research is conducted according to best practice biosecurity and biosafety norms and standards.
 - 1.8.2 Report to the designated agency/institution any Dual Use Research of Concern.

DOMAIN 2: DEVELOPMENT OF NATIONAL STANDARDS FOR BIOSAFETY AND BIOSECURITY

2. Implementation of National Standards for Biosafety and Biosecurity

The BSBS Legal framework authorizes the lead agency/institution to develop National Minimum Standards for biosafety and biosecurity as benchmarks for compliance. The minimum standards should be based on international guidance and evidence based best practices including the most recent versions of the WHO Laboratory Biosafety Manual 4th Edition²², ISO 35001²³, OIE International Standards on Biosafety and Biosecurity Chapters 1.1.4²⁴ and Chapter 2.1.3²⁵ and others as they apply.

The legal instruments to be developed by Member States should reference the need to develop technical and physical capacity to comply with standards that should remain updated through required review and revision at regular intervals. The standards should be accompanied by a checklist that can be used to assess/conduct gap analysis, monitor progress of implementation, and assess compliance.

The Legal instruments to be developed by Member States shall refer to respective national standards to be complied to by facilities that handle pathogens of concern (not on the HCAT), including the WHO Biosafety Manual or others as it applies.

2.1 The BSBS legal framework authorizes the national agency/institution to develop national minimum standards for biosafety and biosecurity that are in line with international standards.

2.1.1 Authorize the lead agency/institution to incorporate available evidence from national and international sources into the national standards every 2-3 years

²² World Health Organization. Laboratory biosafety manual, 4th edition.
<https://www.who.int/publications/item/9789240011311>

²³ International Organization for Standardization. ISO 35001:2019. Biorisk management for laboratories and other related organizations. <https://www.iso.org/standard/71293.html>

²⁴ World Organisation for Animal Health. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Chapter 1.1.4. Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities.
https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.04_BIOSAFETY_BIOSECURITY.pdf

²⁵ World Organisation for Animal Health. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Chapter 2.1.3. Managing Biorisk: Examples of Aligning Risk Management Strategies with Assessed Biorisks.
https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.03_BIOL_AGENT_SPECIF_RA.pdf

- 2.1.2 Authorize the lead agency/institution to set facility biosafety and biosecurity standards in line with control measures determined by risk assessment as guided by the current WHO Laboratory Biosafety Manual²⁶.
- 2.1.3 Authorizes the agency/institution to monitor compliance and enforcement of the national standards.

DOMAIN 3: AUTHORITY FOR BIOLOGICAL RISK ASSESSMENT AUTHORITY FOR BIOLOGICAL RISK ASSESSMENT OF AGENTS AND TOXINS

The BSBS legal framework authorizes the introduction of measures to prevent the proliferation of biological and toxin based weapons; prevention of unintentional exposure to HCATs; control of activities with agents and toxins in order to protect human, animal, plant and the environment. Intentional or un- intentional release of pathogens through unauthorized synthesis or possession of agents and toxins with potential to cause an epidemic shall be prevented. However, authority conferred by the BSBS legal framework shall not hamper international cooperation in materials, equipment and technology for peaceful purposes and shall be in line with UNSCR 1540.

The HCAT list shall be included as an appendix to allow flexibility in amending the list without having to review the entire document. The HCAT list should be reviewed every 2-3 years to account for emergence of new agents/toxins, advances in research and science or whenever there are updates from research, science or emergency of new threats

The agency/institution shall assign authority to determine the risk associated with synthesis, manipulation, storage and transportation of HCATs through a structured process of identifying the agents/toxin, determining who is at risk, severity and likelihood of harm and assessing adequacy of existing control measures. The BSBS legal framework:

- 3.1 Prohibits all activities related to production/manufacture, stockpiling/storage, acquisition, retention/possession, transport and use of biological agents or associated materials for purposes of developing biological weapons of mass destruction.
- 3.2 Authorizes biological risk evaluation of agents and toxins for purposes of generating a national HCAT list. This includes:
 - 3.2.1 Creating a list of prohibited toxins, biological agents, and agents of concern (regulated but not prohibited) as an appendix
 - 3.2.2 Reviewing and updating of the HCAT list every 2-3 years or whenever there are updates from research, science or emergency of new risks
- 3.3 The BSBS Legal framework requires biological risk evaluation to categorize biological agents and toxins based on the following criteria:
 - 3.3.1 Ability to be weaponized

²⁶ World Health Organization. Laboratory biosafety manual, 4th edition.
<https://www.who.int/publications/i/item/9789240011311>

- 3.3.2 Potential for infection
- 3.3.3 Means of transmission.
- 3.3.4 Communicability within a population
- 3.3.5 Severity of harm
- 3.3.6 Availability and effectiveness of preventive measures
- 3.3.7 Availability of effective control measures
- 3.3.8 Availability and effectiveness of medical treatments
- 3.3.9 Eradicated pathogens
- 3.4 The BSBS legal framework authorizes implementation of control measures on identified risks that includes:
 - 3.4.1 Identifying who conducts risk assessments and act upon risks identified.
 - 3.4.2 The use of a hierarchy of controls approach of elimination, substitution, engineering controls, administrative controls and personal protective equipment in the management of identified risks.

DOMAIN 4: REGULATION OF LABORATORY AND FACILITY LEVEL REQUIREMENTS FOR HANDLING AGENTS AND TOXINS OF CONCERN

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

The BSBS legal framework authorizes the designated national agency/institution to regulate laboratories and facilities which handle, manipulate, use, store or transport HCATs which may include hospitals, academic institutions laboratories for animal, plant, and environmental research.

To monitor compliance and to set minimum standards at the facility level, a recognized certification or accreditation program shall be identified. The certification or accreditation process shall involve systematic review of all biosafety and biosecurity features and processes associated with the facility to validate that all facility controls, practices and procedures are in place to minimize the risks associated with handling of hazardous materials.

The BSBS legal framework authorizes:

- 4.1 Authorizes the designated agency/institution to regulate laboratories and facilities that can produce, use, store or transport of HCAT. Legal instrument authorizes designated agency/institution to regulate laboratories and facilities that produce, use, manipulate, transfer or store or destroy/incinerate HCATs.:
- 4.2 The agency/institution to Develop a national system for monitoring compliance with biosafety and biosecurity national standards as stipulated in Domain 2 at the laboratory or institution level including:
 - 4.2.1 The creation of a certification and/or accreditation system in compliance with set national biosafety and biosecurity minimum standards, as stipulated in Domain 2, for laboratory and institutions that produce, use, manipulate, store transfer or

destroy/incinerate HCATS. The certification program to cover, human, animal, plant and environmental,

4.3 Registration with the agency/institution of laboratories or facilities who possess, use, manipulate, store, transfer or destroy/incinerate HCATS.

4.3.1 Registration to be based on compliance to the national minimum standards for biosafety and biosecurity.

4.3.2 Period of validity of the registration to be specified.

4.4 The agency/institution to conduct Inspections and assessments for purposes of checking continued compliance and for renewal of accreditation/certification, registration for laboratories and institutions that possess, use, manipulate, store transfer and destroy/incinerate HCATS. This includes:

4.4.1 Granting the power to the agency/institution to remove accreditation, certification or registration of laboratories and facilities who fail to meet biosafety and biosecurity requirements as stipulated in the national minimum standards.

4.4.2 Assessments for compliance to national minimum standards being conducted by persons trained and certified by a recognized body/institution.

4.4.3 Reporting of incidents/safety breaches related to biosafety and biosecurity of HCATS by laboratories and facilities handling HCATS.

DOMAIN 5: EDUCATION, TRAINING, AND HUMAN RESOURCE REQUIREMENTS FOR PERSONNEL WHO POSSESS, USE, MANIPULATE, STORE, TRANSFER OR DESTROY/INCINERATE HCATS

5 Education, Training, and Human Resource Requirements for Personnel who Possess, Use, Store, Manipulate, Transfer or Destroy/Incinerate HCATS

The BSBS legal framework authorizes the designated agency/institution to regulate requirements for individuals handling HCATS including stipulation of their education, training, and human resource development requirements.

Training and capacity building of personnel at the facility level shall be monitored. Technical and administration staff shall both be trained using tailored training. Pre-service and in-service training shall be supported by certification and registration for technical staff. Tailored training for administration staff will ensure they understand and are able to support implementation of the biosafety and biosecurity requirements.

Training curriculum for biosafety and biosecurity should be broadly defined in the national legal instruments to allow for frequent reviews for continued relevance and applicability. Curriculum shall promote recognition of biosafety and biosecurity as a profession.

The BSBS legal framework authorizes:

- 5.1 Security screening/personnel reliability checks and registration with a recognized and identified body/institution of individuals who possess, use, manipulate, store transfer or destroy/incinerate HCATs. Security screening/reliability checks shall ensure that daily work practices and procedures are being performed by suitable personnel who act in a reliable and trustworthy manner. This includes:
 - 5.1.1 Stipulating the frequency of security screening/personnel reliability checks of individuals.
 - 5.1.2 Penalties associated with individuals who continue to possess, use, manipulate, store transfer or destroy/incinerate HCATs without valid screening and registration records.
 - 5.1.3 Penalties associated with institutions that continue to use individuals without valid screening and registration records.
 - 5.1.4 Addressing the protection of individual health data collected for the purposes of screening and registration.
- 5.2 Prior authorization for personnel who possess, use, manipulate, store, transfer or destroy/incinerate HCATs. This includes licensing with a recognized and identified body/institution for those who possess, use, store or transfer biological agents or toxins.
- 5.3 Biological risk management training and education for individuals who possess, use, manipulate, store or destroy/incinerate HCATs.
- 5.4 Development of biosafety and biosecurity education and training curricula or a framework for training and capacity building in biosafety and biosecurity for both pre-service and in-service training.
 - 5.4.1 Agency identifies institution to develop and regularly review training curricular.
 - 5.4.2 Training and certification to be conducted upon hiring (pre-service) and at specified intervals (in-service)
 - 5.4.3 training and certification to be specifically designed for individuals (laboratory personnel, administrative personnel, and managerial personnel)
- 5.5 Development of a national certification program for personnel in areas of biosafety and biosecurity specialty/expertise as identified by the training and capacity building program.
 - 5.5.1 The agency/institution shall identify the I Institutions/entities who develop, regulate and monitor training program
- 5.6 Development and maintenance of professional standards by the agency/institution.

DOMAIN 6: TRANSFER, STORAGE, DISPOSAL OF HCATS

6 Transfer, Storage, and Disposal of HCATS

The BSBS framework addresses transfer, storage, and disposal of HCATS including pathogens of concern. Transfer requirements shall apply for both local and international transfer. Standards on infrastructural requirements for storage and disposal of hazardous, waste and chemicals shall be specified.

The BSBS framework should provide control and enforcement mechanisms such as penalties for failure to comply as well as requirements related to certification, licensing, and registration.

The requirements shall also apply to repositories and biobanks storing HCATs. Disposal will also include destruction of agents and toxins, including details of the time, place and specified personnel involved in the destruction.

The BSBS legal framework authorizes:

- 6.1 The establishment of control and enforcement mechanisms such as certification, licensing, registration as well as penalties for all laboratories and institutions that transfer, store and dispose biological agents and toxins including pathogens of concern.
- 6.2 Regulation of the storage of HCATs including:
 - 6.2.1 Maintenance of an up-to-date register/inventory of all stored HCATs at all times.
 - 6.2.2 Reporting of inventories of all stored agents and toxins to the designated agency/institution
- 6.3 Regulation of the transfer of biological agents and toxins including:
 - 6.3.1 Reporting of transfers of biological agents and toxins to a designated agency/institution.
 - 6.3.2 Packaging and labelling requirements for all transportations of biological agents and toxins that are in line with other international requirements
 - 6.3.3 Reporting to the designated agency/institution transfers (purchases, sales, disposals) of growth/transport media used for HCATs.
 - 6.3.4 Implementing measures to secure transport of biological agents and toxins by any and all methods of transportation.
- 6.4 Regulation of the safe, secure, and environmentally sound disposal of hazardous and chemical waste resulting from possession, use, storage and transportation of biological agents and toxins. This shall include disposal of carcasses and excretions of animals exposed to high consequence agents and toxins.
 - 6.4.1 The methods of disposal (incineration, burying, composting) shall protect environmental contamination.

ANTICIPATED CHALLENGES AND RECOMMENDATIONS

During the validation meetings, Member State representatives and technical experts identified challenges that Member States may face when using the BSBS Legal Framework along proposed solutions. These identified challenges and the factors set forth below may serve as important discussion items as Member States engage in the process of using the BSBS Legal Framework.

Anticipated Challenge	Proposed Solutions/Recommendations
1. Inadequate financial resources to support establishment/strengthening of designated agency/institution and execution of its oversight roles. Resources will be required for infrastructural, operational, and human functions	• Dedicate budget from government • Provision to receive direct support from other sources with requirement to account to government for all resources received. • Permit the raising and retaining of funds through such activities like penalties, registration, certification and accreditation fees • Resource mobilization through partners
2. Limited resources to implement legal requirements of the legal biosafety and biosecurity e.g., national biosafety and biosecurity standards,	• Dedicate budget from government through the designated ministry • Dedicate resource mobilization/advocacy to lobby groups for support from government and other partners • Avail adequately trained and qualified human resource • Drafting a sustainability plan with budget for 5-10 years
3. Poor infrastructure to comply with Biosafety and Biosecurity requirements of the framework	• Conduct a gap analysis using legal framework requirements/checklist to identify gaps and resources required to upgrade or put in place required infrastructure • Allocate required financial resources required for infrastructural upgrades
4. Limited knowledge and support from biosafety and biosecurity by policy makers	• Conduct socialization and awareness building activities with of policy makers, including parliamentarians, who will support domestication of the framework into law and advocate for resources • Identify policy makers to be champions for the framework and support them with training and tools to advocate for the framework
5. Limited expertise in some Member States to develop and implement some of the biosafety and biosecurity requirements	• Develop, at regional and national level, a training and capacity program to support domestication and implementation for the framework • Promote biosafety and biosecurity as profession to attract more professionals through national curriculum
6. Resistance and limited support from other stakeholders who may currently be responsible for some of the biosafety and biosecurity Aspects	• Conduct inclusive, multisectoral, One Health oriented awareness, training, capacity building and advocacy engagements to clarify roles and responsibilities for all stakeholders
7. Compliance to national standards and attainment of certification and/or accreditation	• Allocate resources to build capacity of laboratories and facilities to comply with national standards



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