



INAUGURAL **ONE HEALTH** CONFERENCE

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Biosafety and Biosecurity Legal Framework

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Presentation Outline

- Background
- Biosafety and Biosecurity Legal Framework
 - Rationale
 - Development Process
 - Framework Domains

Biosafety and Biosecurity Initiative

To strengthen the biosecurity and biosafety systems of African Union Member States to comply with international regulations including the International Health Regulations (IHR 2005), Biological Weapons Convention (BWC), and United Nations Security Council Resolution (UNSCR) 1540 and the GHSA action packages (APP3)

INITIATIVE GOAL

To strengthen the biosecurity and biosafety systems of African Union Member States to comply with international regulations including the International Health Regulations (IHR 2005), Biological Weapons Convention (BWC), and United Nations Security Council Resolution (UNSCR) 1540 and the GHSA action packages (APP3)

OBJECTIVE 1

Develop a Biosafety and Biosecurity Legal Framework for the Africa Region

OBJECTIVE 2

Establish Regional and Continental Biosafety and Biosecurity TWG to coordinate and monitor implementation

OBJECTIVE 3

Establish a Regional Training and Certification Program for Biosafety and Biosecurity Experts

OBJECTIVE 4

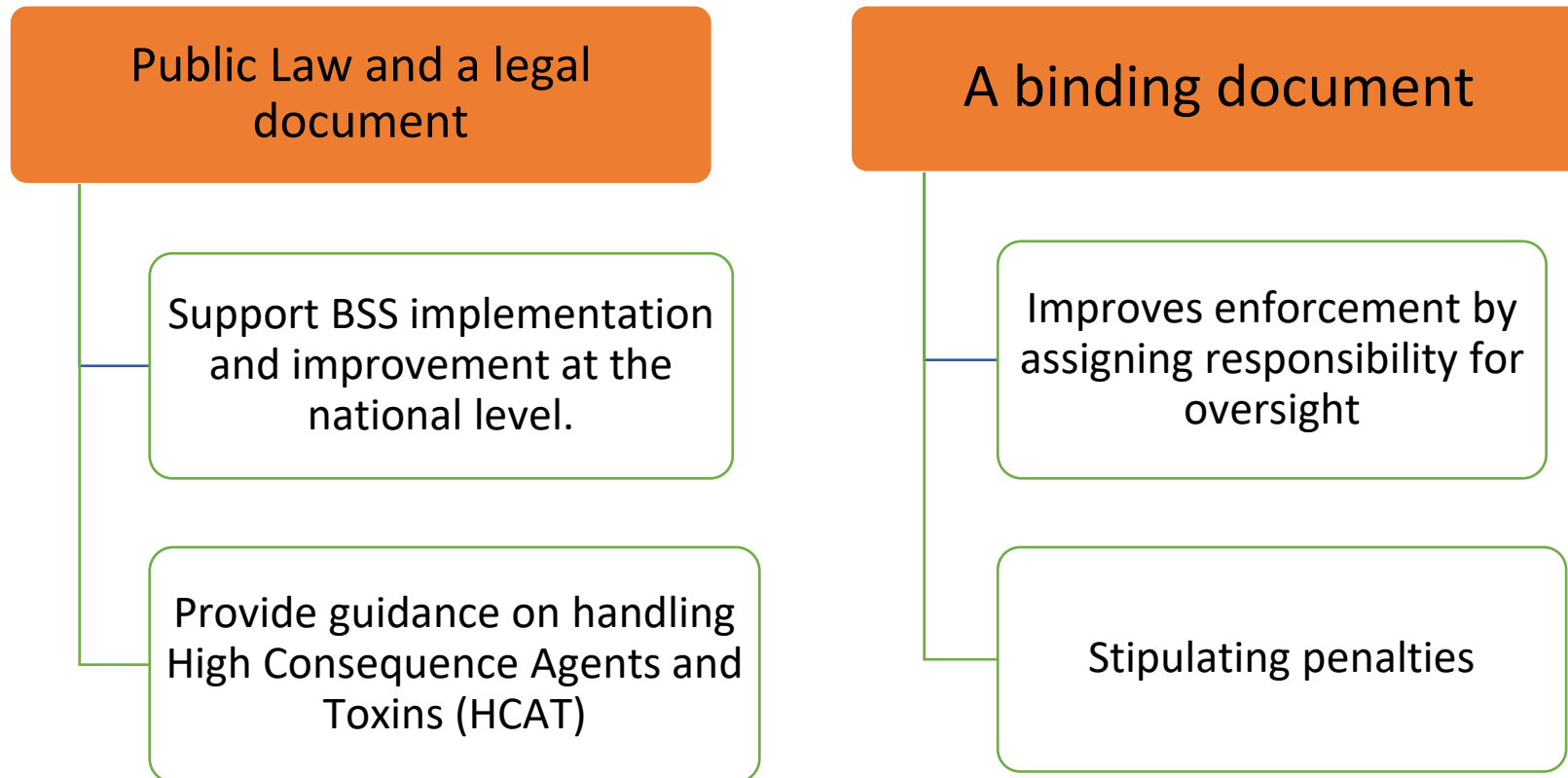
Establish a regulatory and certification framework for institutions handling high risk pathogens

OBJECTIVE 5

Strengthen NPHI and NRL capacities to prevent, detect and respond to Events of public health concern in each MS

Legal Framework – Rationale

Member states Highlighted lack of or inadequate and fragmented legislation, regulations and policy frameworks relevant to biosafety and biosecurity as key to lack of prioritization and improvement of biosafety and biosecurity among Member States



USING THE LEGAL FRAMEWORK

Where a Legal Framework already exists

A guide to review the Member State's existing legal instruments to check their scope, coverage & adequacy

Where no Legal Framework exists

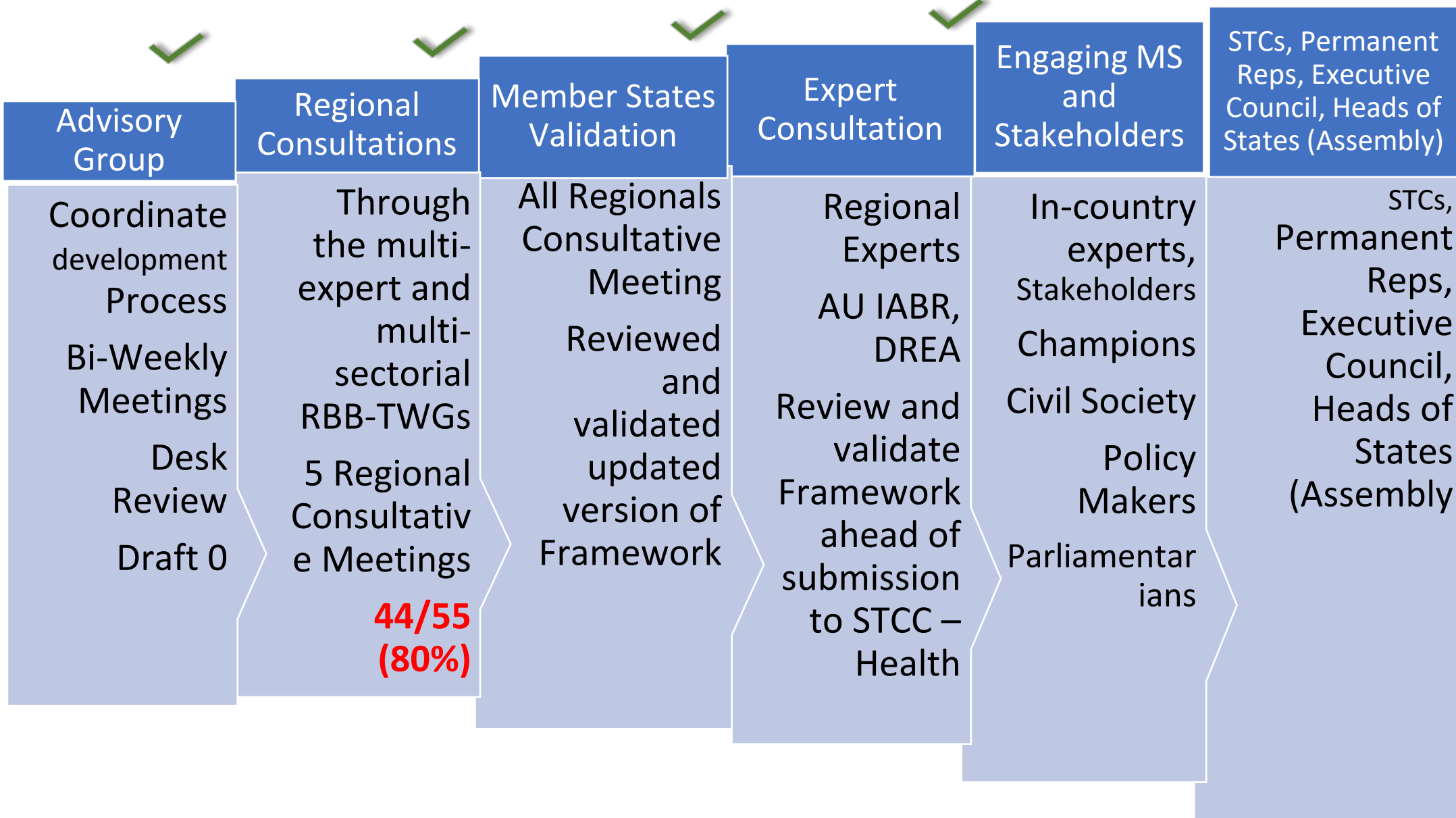
Basis for developing a national BSS legal framework. Member States may adopt and domesticate the framework to address national needs.

Multi-staged Consultative Iterative Process

**Framework Development
July 2020 - May 2021**

**May – October 2021
Advocacy**

**Nov 2021- March 2022
Adoption by AU**



Legal Framework Domains

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**

Domain 7

- **Prohibition of all Activities in the Development, Possession, and Transfer of Biological Agents for the Purpose of Producing Weapons**

Anticipated Challenges and Proposed Solutions

