



Piloting the global guidance framework for the responsible use of the life sciences in Uganda

Technical stakeholders' workshop Report

6-7 March 2024, Kampala



**World Health
Organization**
Uganda

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Abbreviations

Africa CDC	Africa Centers for Disease Control and Prevention
BWC	Biological Weapons Convention
DUR	Dual Use Research
DURC	Dual Use Research of Concern
KPI	Key Performance Indicators
STI	Science Technology and Innovation
TWG	Technical Working Group
WHO	World Health Organization
AFRO	WHO Africa Regional Office

Executive Summary

As a result of the regional workshop to operationalize the global guidance framework for responsible use of life sciences in the WHO African region held in Nairobi, Kenya from 24th to 25th January 2023, Uganda committed to piloting the operationalization of the Global Guidance Framework for the Responsible Use of Life Sciences. Among the strategic actions outlined for this pilot initiative, some pivotal activities identified were sensitization workshops of key national stakeholders on the framework and its implementation.

From 6th to 7th March 2024, a technical stakeholders' workshop was held as a follow-on activity after a national sensitization workshop in November 2023. The aim of the technical workshop was to continue with the sensitization of key stakeholders on the global guidance framework for the responsible use of life sciences and to review a draft roadmap, developed during the November workshop. The workshop convened over 30 technical stakeholders from different sectors including academia, industry, government, and non-governmental organizations. The workshop included structured presentations, informative panel discussions, interactive working group sessions, and comprehensive plenary discussions.

The first session of the workshop commenced with opening remarks stressing the importance of continuity in discussing the framework and achieving tangible outcomes. Presentations highlighted key framework elements, challenges in biorisk governance, and the pilot project's progress. Notably, speakers emphasized strengthening biosafety and biosecurity capacities and dual-use research governance in the country.

In subsequent sessions, stakeholders in different working groups identified relevant stakeholders and their roles. Plenary discussions ensued, resulting in a comprehensive list of stakeholders and their defined roles for effective operationalization. The final session of the workshop focused on reviewing the draft roadmap. Feedback led to refinements, emphasizing alignment with existing structures like the One Health platform. Key strategies included establishing a dual-use research governance committee and advocating for budget allocation and key performance indicators (KPI) inclusion. Stakeholders recommended human resource capacity building, legislative mapping for alignment, assessment of unregulated research, and continued sensitization for effective framework implementation.

The workshop generated significant outcomes, including heightened awareness among participants regarding responsible life sciences use and dual-use research. Additionally, stakeholders' groups and their roles were effectively identified and documented and finally, the draft roadmap underwent refinement, emerging as a current working document for presentation at a high-level stakeholders meeting. This roadmap is aimed at guiding subsequent steps, providing a structured approach for framework implementation.

1. Introduction

WHO published the [global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research](#) (the framework) in 2022. This framework constitutes a systematic guide for Member States in formulating robust policies, regulations, and governance structures for biorisks management and dual-use research governance in the context of the One health approach.

The framework underscores the necessity of strengthening dual-use research governance frameworks by highlighting the importance of nuanced understanding of dual-use concerns. With its extensive set of values and principles, useful six step approach guiding the implementation, and specialized checklists, the framework gives Member States and stakeholders the resources they need to execute it successfully. Furthermore, it incorporates practical scenarios and real-world case studies, which enhances knowledge of the complexities of governance in relation to biorisks and dual-use research.

During the regional workshop to operationalize the framework in the WHO African region (AFRO) held in Nairobi, Kenya from 24 to 25 January 2023, Uganda agreed to pilot the operationalization of the framework starting in August 2023. The experiences and lessons learned from Uganda's pilot are anticipated not only to inform national policies but also to substantively contribute to the broader operationalization of the framework across the WHO African region. Key strategic activities of the action plan to pilot the framework in Uganda were identified. Some of the earmarked activities included sensitization activities of relevant national stakeholders on the framework and the pilot project to create awareness about the framework, assess the relevance of the framework to the country's context and secure ownership and commitment to adopt and operationalize the framework in Uganda.

The first national stakeholder's sensitization workshop was scheduled and took place from 21 to 23 November 2023 at Speke Resort Munyonyo, Kampala, Uganda. At the workshop, over 80 stakeholders from across different areas including human health, animal health, environment, security and defense, academia, industry etc. were sensitized and increased their awareness of the topic of responsible use of life sciences and dual-use research governance. And a draft roadmap was collaboratively developed for the implementation of the global guidance framework for responsible use of life sciences in Uganda.

A technical stakeholders' workshop as a follow-on activity with the aim of reviewing and refining the roadmap and the implementation strategies developed at the national workshop to operationalize the framework ensuring their alignment with the technical landscape and specific challenges in Uganda was scheduled. The workshop took place from 6 to 7 March 2024 at WHO country office, Kampala.

The 2 days workshop comprised key presentations, plenary sessions and working group sessions with a major aim of refining the draft roadmap that was established during the national stakeholder's workshop in November 2023. This workshop aimed to foster active participation and engagement of the technical stakeholders.

2. Objectives of the workshop

- To continue with sensitization of key stakeholders on the global guidance for the responsible use of life sciences and the pilot project.

- To review and refine the draft roadmap developed from the first stakeholders' workshop.

3. Summary of the discussions

The workshop convened 30 technical stakeholders from across different areas including human health, animal health, environment, security and defense, academia, and industry. They were sensitized and increased their awareness of the topic of responsible use of life sciences and dual-use research governance. During the workshop, key stakeholders' groups were identified and their roles defined for effective operationalization of the framework in Uganda. The draft roadmap from the first stakeholders' workshop was reviewed identifying key strategies and practical actions for the effective operationalization of the framework in Uganda.

Session one: workshop opening and objectives of the workshop.

The workshop was opened by Andrew Niwagaba Bakainaga, Country Advisor – Health Systems strengthening from the WHO country office for Uganda. Complementing these opening remarks were additional contributions from Sandra Matinyi, Consultant – Public Health from the WHO country office for Uganda as chair of this session, presented the objectives and expected outcomes of the workshop, its format and working methods.

In the workshop opening remarks, Andrew Niwagaba Bakainaga argued for continuity on the discussion of the framework and encouraged the team to come up with tangible outputs to aid in the operationalization of the framework. He also emphasized that it was a great opportunity for Uganda to pilot the framework and applauded the collaborative nature of the workshop and the need for sustained commitment beyond the workshop.

Sandra Matinyi highlighted the key elements in the framework including sources of risks and the consequences of dual use research. She described the challenges and gaps in governance of biorisks based on global context and also presented tools and mechanisms for their governance. She also emphasized on the need for collaboration and engagement among different stakeholders to address the evolving challenges and major gaps in the governance of biorisks. The summary of the practical tools and mechanisms were presented, including an overview of the six-step approach. Discussions following this presentation emphasized on the need to identify how the existing national laws and guidelines could be aligned with the framework thus customizing it to the national needs which would allow easy integration of the framework into existing structures. The second presentation, led by Andrew Niwagaba Bakainaga introduced the pilot project. Stakeholders were informed that Uganda had agreed to pilot the operationalization of the framework during the AFRO regional workshop held in Nairobi Kenya in January 2023 and the pilot project had started in August 2023 under the coordination of Office of the Prime Minister. He presented objectives of the pilot project that included to assess the feasibility, appropriateness, and applicability of the framework; understand stakeholder perspectives; document lessons learned; identify emerging issues; propose improvement strategies and contribute to the ongoing discourse on responsible use of the life sciences. He provided a progress report on completed priority activities such as the stakeholder field survey that had been completed in October 2023 with the aim of establishing the countries status regarding biosafety, biosecurity and dual-use research governance, the national sensitization workshop of November 2023 where various stakeholders were sensitized on the framework,

and they went on to develop a draft roadmap on how the framework would be domesticated and operationalized in Uganda. This presentation provided insights into the implementation progress of the key strategic activities that had been identified as part of the pilot project.

Joseph Nkodyo, the National Coordinator, Biosafety Biosecurity Program for Uganda Ministry of Health provided a comprehensive overview of biosafety and biosecurity capacity, laws, and regulations. The existing strengths included the existence of the Biosafety and Biosecurity Association of Uganda, accredited laboratories, in service training programs, and national coordination efforts. Areas for strengthening identified included legislation, domestication of some of the treaties and protocols, financing, supervision, and facility certification. To aid in the operationalisation of the framework, he recommended the inclusion of biosecurity and biosafety indicators among the key performance indicators (KPIs) monitored regularly by all Ministries, Departments and Agencies (MDAs) and reported quarterly. More so, the need to fast track the enactment of the biosafety Biosecurity bill and guidelines and strengthen the functionality. He concluded with emphasis on the need for licensing of professionals and institutions at national level, comprehensive training, research and partnerships.

The last presentation was made by Kankya Clovice, professor from Makerere University. His presentation centered on dual use research governance in Uganda. He highlighted the current key considerations and principles for dual-use research governance in Uganda. These include risk assessment to assess the potential risks and benefits associated with the research, risk management involving the implementation of measures to mitigate and control the identified risks, ethical considerations entailing the addressing of ethical implications and potential harm to individuals, communities, and the environment and transparency aimed at promoting openness and communication about Dual Use Research of Concern (DURC) to relevant stakeholders. Finally, he indicated the need to foster a One Health approach for consolidated effort from all sectors for effective dual-use research governance.

Session two: Stakeholders' groups identification and their roles in the operationalization of the framework

This session was led by Morgan Otitia, Project Officer from the Infectious Diseases Institute. Participants were divided into two predetermined working groups, each assigned with identifying relevant stakeholders, their mandate and the role in operationalization of the framework.

Following these group discussions, a plenary session was convened to allow the working groups to share and collectively discuss the findings from each group. This collaborative approach encouraged a comprehensive exploration of the different stakeholders and a list of stakeholders, and their roles was established.

The identified stakeholder groups were policy makers, regulators, academia, other implementers, development partners, private sector and civil society and the public. The stakeholders defined the roles of each group as below:

- Policy makers – to create and endorse national policies and strategies for mitigating biorisks and dual-use research governance, ensuring legislative support and resource allocation.

- Regulators – to enforce laws and regulations, conduct inspections and audits, manage approvals and licenses, and ensure compliance.
- Academia – to conduct research responsibly, provide education and training on biorisk mitigation and dual use research, contribute expert input to policy development, and promote ethical research standards.
- Development partners – to provide financial, technical, and strategic support, including funding, technical assistance, capacity building, and sharing best practices.
- Implementers – to conduct dual use research responsibly, ensure compliance with established regulations, perform risk assessments, implement mitigation measures, and maintain documentation.
- Private sector and civil society – to innovate and provide solutions for dual use research risk mitigation, conduct research responsibly, educate the public, advocate for strong policies, and collaborate with other stakeholders.

Session three: Review of the draft roadmap for the implementation and operationalization of the global guidance framework for the responsible use of the life sciences in Uganda

The afternoon of day three was dedicated to the presentation and review of the draft roadmap. The rapporteurs lead in presenting the draft roadmap. Through the feedback from the technical stakeholders, changes were made to the draft road map to clearly define the objectives. The significant changes were made emphasizing the need to consider already existing structures such as the already existing One Health platform. These changes were included in the draft roadmap. The roadmap was refined through collaborative efforts to ensure that it accurately reflected the collective insights and recommendations of the diverse stakeholders present, contributing to a comprehensive and well-informed plan for the operationalization of the Global Guidance Framework in Uganda. Key strategies for operationalization of the framework in Uganda based on the review included; establishment of a dual use research governance steering committee to integrate the dual use research within the existing One Health Strategic Plan to guide the implementation and operationalization of the framework, to support advocacy for increased budget allocation and funding opportunities for research to include Dual Use Research governance, and advocacy for inclusion of the dual use research governance KPIs into the national monitoring and evaluation framework to enhance timely reporting on dual use research.

To facilitate effective operationalization of the framework, the technical stakeholders had the following recommendations;

- The need for human resource capacity building in different sectors.
- There is a need for a comprehensive legislative mapping to identify how the existing laws align with framework subsequently facilitating easy customization of the framework.
- The need to conduct an assessment to identify unregulated research such as research by herbalists and a number of do it yourself (DIY) research communities and establish mechanisms to regulate their research.
- Continued sensitisation of all regulators and key stakeholders to ease their understanding of the framework and cultivate ownership and commitment to operationalize the framework.

4. Outcomes of the workshop

The workshop yielded valuable outcomes for the stakeholders involved. Firstly, there was an increase in awareness regarding the responsible use of life sciences and dual-use research among the participants. This heightened awareness is crucial for fostering a shared understanding and commitment to responsible use of life sciences research.

Additionally, the workshop facilitated the identification and documentation of stakeholders' groups and their roles in the operationalization of the framework.

Furthermore, the draft roadmap was refined to serve as a current working document to be presented at the high-level stakeholders meeting for discussion and adoption to guide the subsequent steps in the operationalization of the framework.

5. Next steps: Immediate actions and follow-up activities

Following the technical stakeholders' workshop, the reviewed roadmap was to be presented at the high-level stakeholders meeting for discussion and decision on the key strategies that would be implemented to domesticate and operationalize the framework in Uganda.

References

1. Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/362313>, accessed 13 February 2023).
2. [Regional workshop to operationalize the global guidance framework for the responsible use of the life sciences in the WHO African Region](#)
3. Draft Road map from the first national stakeholders sensitization workshop

Annex 1

List of participants from the technical stakeholders' workshop to pilot the global guidance framework for the responsible use of life sciences in Uganda from 06 to 07 March 2024.

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