Regional workshop to operationalize the global guidance framework for the responsible use of the life sciences in the WHO African Region

Meeting report

Nairobi, Kenya, 24–25 January 2023
Regional workshop to operationalize the global guidance framework for the responsible use of the life sciences in the WHO African Region

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<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>Africa CDC</td>
<td>Africa Centres for Disease Control and Prevention</td>
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<tr>
<td>ECHO DEVCO</td>
<td>European Commission Humanitarian aid and Civil Protection department, European Commission Directorate-General for International Cooperation and Development</td>
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<td>EPS</td>
<td>Emerging Technologies, Research Prioritisation and Support</td>
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<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
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<td>NAPHS</td>
<td>National Action Planning for Health Security</td>
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<td>NBFs</td>
<td>National Biosafety Frameworks</td>
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<tr>
<td>OH JPA</td>
<td>One Health Joint Plan of Action</td>
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<td>SDGs</td>
<td>Sustainable Development Goals</td>
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<tr>
<td>TWG</td>
<td>technical working group</td>
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<tr>
<td>UNEP</td>
<td>United Nations Environment Programme</td>
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<td>WOAH</td>
<td>World Organization for Animal Health</td>
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Executive summary

From 24 to 25 January 2023, 38 multidisciplinary and multisectoral experts met in Nairobi, Kenya. The workshop, which was organized by the WHO Science Division, in collaboration with the WHO Regional Office for Africa and the Africa Centres for Disease Control and Prevention (Africa CDC), brought together representatives from seven countries – Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ghana, Kenya, Rwanda and Uganda –, representatives of the Food and Agriculture Organization of the United Nations (FAO); the United Nations Environment Programme (UNEP) and the World Organization for Animal Health (WOAH)); former and current Chairs of the Africa CDC Sub-Regional Technical Working Groups on Biosafety and Biosecurity from North, East, West and Southern Africa; representatives of Africa CDC and the WHO Secretariat.

The objectives of the two-day technical workshop were to: present the framework and other related existing regional initiatives; facilitate the sharing of knowledge and experience of countries on the challenges and needs in mitigating biorisks and governing dual-use research; strengthen collaboration among multiple and multidisciplinary stakeholders within the WHO African Region; test specific elements of the framework, including the six-step approach and the checklist for the national governments, and identifying the needs for additional toolkits or regional guidance; and recommend concrete actions for the roll-out of a national implementation of the framework.

The workshop was intended to consolidate, build on knowledge and practice, and stimulate increased engagement from Member States and regional champions in the area of responsible use of the life sciences. Conducted in English and French with simultaneous translation, it was organized around a set of different types of sessions (plenary sessions, panel sessions and working groups sessions) to facilitate a participatory and interactive working method.

The meeting participants gained increased awareness on the topic of responsible use of life sciences and dual-use research; identified specific needs and challenges of African countries; and adopted a set of recommendations for rolling out the implementation of the framework at country and regional levels. Next steps will include, but not limited to, the selection of a pilot country to implement the framework; the mapping of existing elements and gaps to start implementing the framework at country level; a situation analysis to determine the level of awareness on biosafety, biosecurity and dual-use research at the national level; the development of advocacy materials to support country sensitization and awareness-raising activities; and the continuation of engagement with participants through the setting up a virtual quarterly meeting to facilitate communication on key events and updates.
Section 1. Background

Life sciences research and associated technologies play a critical role in improving global health, supporting healthier populations worldwide and promoting health equity for all to achieve the health-related United Nations Sustainable Development Goals (SDGs). However, developments and advances in the life sciences also pose safety and security risks. In response to the rapid developments in life sciences and emerging technologies, cheaper technologies and ease of access, the diversity of actors and sectors and the lack of awareness and gaps in the governance of biorisks, WHO published the Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research (hereinafter the framework) (1).

The framework is the first-of-its-kind comprehensive global guidance document that aims to inform the development of national frameworks and approaches for mitigating biorisks and governing dual-use research while harnessing the power of life sciences for global health. It provides a set of values and principles to guide decision making; examples of tools and mechanisms for Member States and key stakeholders; a practical six-step approach for implementation; checklists for various stakeholders; scenarios and case studies on the governance of biorisks and dual-use research.

The governance of biorisks is an issue that should engage all countries, although countries will have different contexts, needs and starting points. The framework underlines that there is no one-size-fits-all approach to mitigate biorisks and governing dual-use research. Different tools and mechanisms (that is formal and informal) can be used to manage these risks. The tools and mechanisms chosen will depend on the particular stakeholders, goals and contexts, but should be complementary and mutually reinforcing. The framework is a global guidance framework that needs to be contextualized to the needs and priorities of different audiences.

The framework raises awareness about the importance of undertaking biorisk management within the context of the One Health approach to optimize the health of people, animals and ecosystems. Given the rapidly evolving challenges, mitigating biorisks and governing dual-use research is a shared responsibility that requires a coordinated and multidisciplinary approach that fosters cross-disciplinary policies and actions, covering humans, nonhuman animals, plants and agriculture, and the environment.

This regional workshop to operationalize the framework in the WHO African Region was the first activity in a series to move the framework towards implementation and adaptation to regional and countries’ needs and priorities.
Section 2. Objectives of the workshop

The objectives of the two-day technical workshop were to:

- present the framework and other related existing regional initiatives;
- facilitate the sharing of knowledge and experience of countries on the challenges and needs in mitigating biorisks and governing dual-use research;
- strengthen collaboration among multiple and multidisciplinary stakeholders within the WHO African Region;
- test specific elements of the framework, including the six-step approach and the checklist for the national governments, and identifying the needs for additional toolkits or regional guidance; and
- recommend concrete actions for the roll-out of a national implementation of the framework.

The workshop was intended to consolidate, build on knowledge and practice, and stimulate increased engagement from Member States and regional champions in the area of responsible use of the life sciences. Conducted in English and French with simultaneous translation, it was organized around a set of different types of sessions (plenary sessions, panel sessions and working groups sessions) to facilitate a participatory and interactive working method.

Section 3. Summary of discussions

From 24 to 25 January 2023, 38 multidisciplinary and multisectoral experts met in Nairobi, Kenya. The workshop, which was organized by the WHO Science Division, in collaboration with the WHO Regional Office for Africa and the Africa Centres for Disease Control and Prevention (Africa CDC), brought together representatives from seven countries – Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ghana, Kenya, Rwanda and Uganda –, representatives of the Food and Agriculture Organization (FAO); the United Nations Environment Programme (UNEP) and the World Organization for Animal Health (WOAH); former and current Chairs of the Africa CDC Sub-Regional Technical Working Groups on Biosafety and Biosecurity from North, East, West and Southern Africa; representatives of Africa CDC and the WHO Secretariat (Annex 1).

In the first session, which was chaired by Joseph Okeibunor, WHO Regional Office for Africa, participants were welcomed by Dr Sultani Matendechero, Head of Kenya National Public Health Institute represented the Director General, Ministry of Health of Kenya; Peter Borus, WHO Country Office for Kenya; Dativa Aliddeki, Africa CDC Eastern Regional Collaborating Center; Annie Brunton, Global Affairs Canada; and Anna Laura Ross, WHO Science Division. Welcoming remarks highlighted the importance of the governance of health research in Africa and the critical role of the life sciences but also the recognition of the risks associated with innovation. It was also noted that biological threats impact all countries, but the nature of threats vary by country. The important role of partnerships and multiple sector coordination to mitigate biorisks and governing dual-use research was emphasized, and this especially given the current...
trends of globalization, international trade and travel, which require collective engagement and frameworks for a safer future. The meeting participants also heard a presentation on the objectives and expected outcomes of the meeting as well as its format and working methods. Participants agreed with the proposed agenda and rapporteurs were identified.¹

At its second session, which was chaired by Samuel Wakhusama, WOAH, participants were briefed on the key terminologies of dual-use research and biorisks, on the framework (1) and its main elements. Key considerations about the implementation of the framework included the recognition that there is no-one-size fits all approach and that biorisk management is a shared responsibility. The session also included presentations providing an overview of existing and new strategies and frameworks on biorisks and dual-use research perspectives in the WHO African Region (2) and of the Signature Initiative to Mitigate Biological Threats in Africa (3). Participants heard that research is an integral part of health development and were briefed on the WHO African Regional Strategy on Research for Health, its guiding principles and monitoring and evaluation framework. The session also heard about the Biosafety and Biosecurity initiative of Africa CDC and updates on 5 strategic priority areas.

Following the presentations, a panel session was held to discuss countries’ strengths and opportunities, challenges and gaps, needs and priorities in anticipating, preventing, mitigating biorisks and governing dual-use research. To facilitate the discussion for this session, preliminary questions had been sent to countries prior to the workshop with the invitation to share information on their respective countries’ situations on biorisk management. Representatives from two countries, Dr Kennedy Yatich, Kenya and Dr Atwiine Atek Kagirita, Uganda, shared information on the current countries’ situations. This was followed by interactive exchanges and discussions.

In the afternoon of the first day, at the third session, which was chaired by Joshua Kimutai, FAO, participants were briefed on two specific tools for implementing the framework: the six-step approach² and the checklist for national governments³. For each step of this six-step approach, a list of key considerations and questions has been suggested. The checklist is not prescriptive nor exhaustive. It was noted that the six-step approach and the checklist are interconnected and adaptable to different needs and audiences.

Participants then broke into working groups (Annex 2) to discuss and provide feedback on the six-step approach and the checklist for national governments of the framework; on their needs for additional toolkits and regional guidance and for mitigating biorisks and governing dual-use research.

¹ For the first day: Dr Anne Cécile Zoung-Kany Epse Bissek, Cameroun; Dr Soufiana Kaba, Côte d’Ivoire; Dr Ali Asy, Egypt and Mr Roland Taremwa, Uganda. For the second day: Dr Donald I. Ofili, Nigeria and Professor Dieudonné Nyembue Tshipukane, République démocratique du Congo.
² The six-step approach, pp. 78-79 (1).
³ The checklist for national governments, pp. 84-87 (1).
Key elements identified by the working groups to contextualize the framework included: the need for advocating and sensitizing high-level authorities using the report of the workshop; the designation of a national entity or working group charged with strategic coordination and oversight of the One Health approach; the need for national self-assessment and gaps analysis and to start the six-step approach process with the step of stakeholder mapping. Participants also discussed key considerations to be considered to contextualize the checklist for national governments in different contexts and settings to start implementing the framework. Generally, the working groups recognized the value of six-step approach and the checklist for national governments.

The second day of workshop, which was chaired by Alex Owusu-Biney, UNEP, started with a panel session with One Health partners that provided perspectives on biorisks and dual-use research from a One Health approach in the WHO African region. Joshua Kimutai, FAO, Alex Owusu-Biney, UNEP and Samuel Wakhusama, WOAH, shared viewpoints in a session which was moderated by Anna Laura Ross.

Among the key points discussed were: the importance of using existing One Health platforms, One Health multi-sectoral coordination mechanisms, and the One Health Joint Plan of Action (OH JPA); leveraging existing frameworks on laboratory biosafety and biosecurity and oversight of research in the life sciences (such as the National Biosafety Frameworks (NBFs) developed to assist member states to implement the Cartagena Protocol on Biosafety); to integrate risk assessment on dual-use into existing standard risk assessment procedures; laboratory assessment tools (for example the FAO Laboratory Mapping Tool and FAO Biosecurity Toolkit); training programs and regional learning hubs (such as Biosafety Clearing House Virtual learning environment developed by UNEP and the FAO Virtual Learning Centers) to mainstream awareness and to champion the responsible use of the life sciences, dual-use research and to amplify biorisk management capacities at regional and national levels. The need for strong public awareness, communication, information sharing and education on biosafety, biosecurity and dual-use research among all the sectors and stakeholders in the context of the One Health approach was underlined.

The rest of the second day was devoted to two working group sessions (Annex 2) where participants discussed and identified their needs and priorities for mitigating biorisks and governing dual-use research and the actions and recommendations for the rolling-out of the national implementation of the framework. To facilitate the reporting, three areas for actions and recommendations were suggested: (i) effective information sharing on the regional implementation of the framework; (ii) increasing partnerships and ensuring synergies with other relevant regional initiatives; and (iii) mobilizing resources to operationalize the framework in concrete and sustainable ways. In summary, key points included:
• Among the needs and priorities, participants underlined: the need to create awareness among multiple key stakeholders (such as high-level authorities, researchers in human-veterinary-environmental health, civil society, law enforcement, legislators); develop multisectoral coordination mechanisms; carry out situation analysis tool to map existing frameworks, capacities and infrastructures; scale up virtual learning centres and partner with universities to integrate this topic in their course; establish a pool of experts at country and regional levels; strengthen funding and capacities, including ethics committees on this topic; develop refresher trainings; and undertake monitoring and evaluation of implementation.

• Among the challenges, the working groups identified: policy challenges (for example lack of high-political buy-in); coordination challenges (such as weakness of multisectoral coordination (such as lack of mandate, insufficient resources allocated to operation); and partnerships and capacities challenges, including ethical and research oversight bodies.

• Regarding the strengths and opportunities for the rolling-out of the national implementation of the framework, the working groups identified the following elements: commitment of governments to be involved in issues of biosecurity, biosecurity and dual research; the establishment of One Health mechanisms in countries; the existence of the Technical Working Groups at country and regional levels; the partnerships with Africa CDC, FAO, UNEP and WHO; the availability of communication mechanisms with multiple platforms; the success story countries for learning and benchmarking; and the increased drive towards research in Africa.

• In terms of concrete actions for the roll-out of the framework, working groups identified several elements including: use the workshop report to brief governments; circulate advocacy materials prepared in collaboration with WHO; WHO to prepare a concept of intent for roll-outing the framework; involve the regional biosafety and biosafety Technical Working Groups (TWGs) on the framework and cascading down to country-level biosafety and biosafety TWGs; hold a country stakeholder inception meeting; identify a lead agency or unit with convening power to coordinate the rollout and for the coordination of biological risks, biosecurity, biosafety and dual research; integrate dual-use research in countries’ National Action Planning for Health Security (NAPHS); map all relevant regional and country partners and resources across partners at country and regional levels and identify centres of excellence; and develop an action plan.

• Among the key recommendations for countries to accelerate the effective implementation of the framework, the working groups identified several elements including: seek governments’ commitment to implement the framework; create and formalize a sectoral and multisectoral coordination framework; advocate with WHO for consultation with other partners involved in the implementation of framework; advocate at regional and country TWG level; strengthen structures for peer-review,
approval and publication of research; identify advocacy champions across stakeholder groups; establish catalytic/seed funding for DUR; establish national secretariat and institutional focal points charged with monitoring and reporting on progress at national, regional and global levels.

In parallel to the second working group discussions, the meeting of partners (Annex 3) provided an opportunity to strategically discuss the mobilization of technical and financial resources needed to implement the framework in the African region.

- Key discussion points included: the need to synergize and support existing biorisk management structures; to develop common action plan among collaboration partners and common goals and strategic objectives; to leverage on existing initiatives and programs that are already funded (for example, the European Commission Humanitarian aid and Civil Protection department, European Commission Directorate-General for International Cooperation and Development (ECHO DEVCO) and the OH JPA); the need for high level advocacy and sensitization targeting policy makers; strengthen capacity building efforts through the regional centers of excellence (training and certification programs); the need for mapping existing frameworks across sectors; and to use biorisk management and dual use champions for advocacy.

Section 4. Outcomes

The meeting participants gained increased awareness on the topic of responsible use of life sciences and dual-use research; identified specific needs and challenges of African countries; and adopted a set of recommendations for rolling out the implementation of the framework at country and regional levels.

In the final plenary session, participants discussed and agreed on a set of practical recommendations on the three above areas and others as relevant. These are listed in order of their appearance in the discussion.

- do a mapping exercise at country level to map: existing legislations, frameworks, guidelines and regulations at country and regional levels; existing capacities in terms of infrastructure, existing structures, human resources; and the level of awareness on biosafety and biosecurity. The TWG at country level can be used for this mapping. Surveys and situation analysis can be used to determine level of awareness.
- do a capacity assessment on biosafety and biosecurity at country and regional levels;
- produce the report of this workshop to sensitize the decision-making authority and set up the sectoral and multisectoral framework for implementation. The availability of both French and English documents, including the framework, was also underlined.
• develop advocacy materials such as advocacy briefs, role play on biosafety, biosecurity and dual-use research and a short awareness-raising film on the impact of dual-use research; and simplify the messaging for the public for maximum impact;
• develop degree programs or post-graduate degree programmes on biosafety in universities as in Kenya, Uganda and Mali;
• facilitate communication with the different experts and regional champions who have participated in this workshop through different means;
• hold quarterly virtual meeting with recordings available for subsequent access; and
• appoint regional champions on dual-use research.

Section 5. Next steps

Next steps will include, but not limited to, the selection of a pilot country to implement the framework; the mapping of existing elements and gaps to start implementing the framework at country level; a situation analysis to determine the level of awareness on biosafety, biosecurity and dual-use research at the national level; the development of advocacy materials to support country sensitization and awareness-raising activities; and the continuation of engagement with participants through the setting up a virtual quarterly meeting, the creation of a WhatsApp group, and regular email communications on key events or updates.

The Emerging Technologies, Research Prioritisation and Support (EPS) unit will continue to consult with relevant individuals, groups and the WHO regions, on the implementation of the framework in the coming months.
References


Annex 1. List of participants

Regional workshop to operationalize the Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research in the WHO African region, Nairobi, Kenya, 24-25 January 2023

**Cameroun**

Dr Georges Alain Etoundi Mballa  
Directeur de la Lutte contre la Maladie, les Epidémies et les Pandémies  
Ministère de la Santé  
Yaoundé

Professeure Josephine Ngo Mbing Epse Pegnyemb  
Chef de la Cellule de la Promotion de la Recherche et de Développement des Pharmacopées Traditionnelles  
Ministère de la Santé  
Yaoundé

Dr Anne Cécile Zoung-Kanyi Epse Bissek  
Chef de la Division de la Recherche Opérationnelle en Santé  
Ministère de la Santé  
Yaoundé

**Côte d'Ivoire**

Dr Soufiana Kaba  
Coordonnateur du Projet d’Amélioration de la Santé Animale et de l’Hygiène Publique Vétérinaire (PASA-HPV)  
Ministère des Ressources Animales et Halieutiques  
Abidjan

Professeur Gnomblessom Georges Tiahou  
Sous-Directeur de la recherche  
Ministère de la Santé de l’Hygiène Publique et de la Couverture Maladie Universelle  
Abidjan

Dr Yro Hyacinthe Tie  
Directeur de la Qualité de l’Environnement et de la Prévention des Risques,  
Ministère de l’Environnement et du Développement Durable  
Abidjan

**Ghana**

Dr Abraham Oduro  
Director for Research & Development  
Ghana Health Service  
Accra
Mr Kwamena Essilfie Quaison
Director of the Science, Technology and Innovation
Directorate of the Ministry of the Ministry of Environment, Science, Technology and Innovation (MESTI)
Accra

Kenya
Dr Jean Gitau
Senior Officer
Global Health Security, Ministry of Health
Nairobi

Dr Kanana Kimonye
Head
Global Health Security, Ministry of Health
Nairobi

Dr Sultani Matendecherero
Head of Kenya National Public Health Institute
Nairobi

République démocratique du Congo
Mme Eugénie Molengo Mokombo
Chef de Bureau en charge des Institutions Humanitaires, Sociales et de l’Organisation Mondiale de la Santé (OMS) à la Direction des Organisation Internationales
Ministère des Affaires Etrangères
Kinshasa

Mr Gilbert Ahoka Tambeke
Chargé d’Études en charge des Questions de Santé au Cabinet du Vice-Premier Ministre
Ministère des Affaires Etrangères
Kinshasa

Professeur Dieudonné Nyembue Tshipukane
Directeur Général de l’Institut de Recherche en Sciences de la Santé
Ministère de la Recherche Scientifique et Innovation Technologique
Kinshasa

Rwanda
Mr Jacques Maniriho
One Health Coordination Specialist
Ministry of Health
Kigali
Dr Erigene Rutayisire
Senior Lecturer of Public Health School of Public Health
Kigali

**Uganda**

Dr Atwiine Atek Kagirita
Former Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa
Kampala

Mr Roland Taremwa
Program Specialist, Monitoring and Evaluation
Office of the Prime Minister
Kampala

Mr Emmanuel Turyatunga
Assistant Commissioner, Monitoring and Evaluation
Office of the Prime Minister
Kampala

Mr Dominic Twesigomwe
Director
National Counter Terrorism Center
Kampala

**Africa Center for Disease Control and Prevention (Africa CDC)**

Ms Dativa Maria Aliddeki
Event-Based Surveillance Analyst - Eastern RCC, Africa Center for Disease Control
Nairobi

Dr Jaurès Arnaud Noumedem Kenfack (virtual participation)
Biosafety and Biosecurity Technical Officer
West Africa RCC of Africa CDC
Abuja
Nigeria

**Regional Biosafety and Biosecurity Technical Working Group Africa CDC, North Africa**

Dr Ali Asy
Professor of Pharmacology
Animal Health Research Institute, Agriculture Research Center (ARC)
Benha
Egypt
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, North Africa
Regional Biosafety and Biosecurity Technical Working Group Africa CDC, Southern Africa

Mr Mabusetsa Joseph Makalo
Senior Laboratory Technologist
Lesotho Central Veterinary Laboratory, Department of Livestock Services
Maseru
Lesotho
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, Southern Africa

Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa

Dr Kennedy Yatich
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa
Nairobi
Kenya

Regional Biosafety and Biosecurity Technical Working Group Africa CDC, West Africa

Dr Donald I. Ofili
Director and Deputy Registrar
Medical Laboratory Science Council of Nigeria
Abuja
Nigeria
Chair, Regional Biosafety and Biosecurity Technical Working Group for West Africa

Food and Agriculture Organization (FAO) Regional Office Nairobi

Mr Joshua Kimutai
Regional Laboratory Specialist
FAO
Nairobi
Kenya

United Nations Environment Programme (UNEP), Nairobi

Mr Alex Owusu-Biney
Portfolio Manager, Biosafety
GEF Coordination, Ecosystems Division
Nairobi
Kenya

World Health Organization for Animal Health (WHOA), Nairobi

Dr Samuel Wakhusama
WOAH Sub-Regional Representative for Eastern Africa
Nairobi
Kenya
**WHO Country Office for Kenya**

Mr Peter Borus  
Scientist  
Nairobi

Dr Esther Ngina Kisangau  
Country Readiness and IHR focal point for Kenya  
Emergency Preparedness and Response, WHO Health Emergency programme  
Nairobi

Mr Charles Muitherero  
Data Manager  
Nairobi

Ms Njoki Shamim  
Programme Assistant  
Nairobi

**WHO Country Office for Uganda**

Dr Niwagaba Andrew Bakainaga  
Country Advisor  
Kampala

**WHO Country Office for Somalia**

Dr Dan Mogaka  
Monitoring and Evaluation Officer and One Health Catalyst  
Great Horn of Africa Food insecurity and Health Unit  
WHO Health Emergency Programme

**WHO Regional Office for Africa**

Dr Joseph Chukwudi Okeibunor  
Lead, Research, Development and Innovations team (including Digital Health)  
Assistant Regional Director Cluster  
Brazzaville  
Congo

Ms Mireille Ch. N. Mavoungoud  
Administrative assistant  
Brazzaville  
Congo
**WHO headquarters**

Dr Soatiana Cathycia Rajatonirina  
Technical Officer  
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division  
Geneva  
Switzerland

Dr Anna Laura Ross  
Unit Head  
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division  
Geneva  
Switzerland

Dr Emmanuelle Tuerlings  
Technical Officer  
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division  
Switzerland

**Observer**

Annie Brunton  
Deputy Head of International Cooperation - Somalia  
Canada’s High Commission to Kenya, Nairobi  
Global Affairs Canada | Affaires Mondiales Canada
Annex 2. Working groups

**Group work session 1 and 2**

**Group work A**

Dr Georges Alain Etoundi Mballa  
Directeur de la Lutte contre la Maladie, les Epidémies et les Pandémies  
Ministère de la Santé  
Yaoundé  
Cameroun

Dr Soufiana Kaba (Rapporteur for session 2)  
Coordonnateur du Projet d’Amélioration de la Santé Animale et de l’Hygiène Publique Vétérinaire (PASA-HPV)  
Ministère des Ressources Animales et Halieutiques  
Abidjan  
Côte d’Ivoire

Mme Eugénie Molengo Mokombo  
Chef de Bureau en charge des Institutions Humanitaires, Sociales et de l’Organisation Mondiale de la Santé (OMS) à la Direction des Organisation Internationales  
Ministère des Affaires Etrangères  
Kinshasa  
République démocratique du Congo

Professeure Josephine Ngo Mbing Epse Pegnyemb (Rapporteur for session 1)  
Chef de la Cellule de la Promotion de la Recherche et de Développement des Pharmacopées Traditionnelles  
Ministère de la Santé  
Yaoundé  
Cameroun

Dr Joseph Chukwudi Okeibunor (Facilitator)  
Lead  
Research, Development and Innovations team (including Digital Health)  
Assistant Regional Director Cluster  
WHO Regional Office for Africa  
Brazzaville  
Congo

Dr Soatiana Cathycia Rajatonirina (Facilitator)  
Technical Officer  
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division  
WHO headquarters  
Geneva  
Switzerland
Mr Gilbert Ahoka Tambekte
Chargé d'Etudes en charge des Questions de Santé au Cabinet du Vice-Premier Ministre
Ministère des Affaires Étrangères
Kinshasa
République démocratique du Congo

Professeur Gnomblessom Georges Tiahou
Sous-Directeur de la recherche
Ministère de la Santé de l’Hygiène Publique et de la Couverture Maladie Universelle
Abidjan
Côte d’Ivoire

Dr Yro Hyacinthe Tie
Directeur de la Qualité de l’Environnement et de la Prévention des Risques
Ministère de l’Environnement et du Développement Durable
Abidjan
Côte d’Ivoire

Professeur Dieudonné Nyembue Tshipukane
Directeur Général de l’Institut de Recherche en Sciences de la Santé
Ministère de la Recherche Scientifique et Innovation Technologique
Kinshasa
République démocratique du Congo

Dr Anne Cécile Zoung-Kanyi Epse Bissek (Chair)
Chef de la Division de la Recherche Opérationnelle en Santé
Ministère de la Santé
Yaoundé
Cameroun

**Group work B**

Mr Joshua Kimutai (Facilitator)
Regional Laboratory Specialist
FAO
Nairobi
Kenya

Mr Mabusetsa Joseph Makalo
Senior Laboratory Technologist
Lesotho Central Veterinary Laboratory, Department of Livestock Services
Maseru
Lesotho
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, Southern Africa
Dr Dan Mogaka  
Monitoring and Evaluation Officer and One Health Catalyst  
Great Horn of Africa Food insecurity and Health Unit  
WHO Health Emergency Programme  
WHO Country Office for Somalia

Mr Charles Muitherero  
Data Manager  
WHO Country Office for Kenya  
Nairobi  
Kenya

Dr Abraham Oduro  
Director for Research and Development  
Ghana Health Service  
Accra  
Ghana

Dr Erigene Rutayisire  
Senior Lecturer of Public Health School of Public Health  
Kigali  
Rwanda

Mr Roland Taremwa (Rapporteur)  
Program Specialist, Monitoring and Evaluation  
Office of the Prime Minister  
Kampala  
Uganda

Dr Emmanuelle Tuerlings (Facilitator)  
Technical Officer  
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division  
WHO headquarters  
Geneva  
Switzerland

Mr Emmanuel Turyatunga (Chair)  
Assistant Commissioner, Monitoring and Evaluation  
Office of the Prime Minister  
Kampala  
Uganda

Dr Samuel Wakhusama (Facilitator)  
WOAH Sub-Regional Representative for Eastern Africa  
Nairobi  
Kenya
Dr Kennedy Yatich  
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa  
Nairobi  
Kenya

**Group work C**

Dr Ali Asy (Chair for session 1 and 2 and Rapporteur for session 1)  
Professor of Pharmacology  
Animal Health Research Institute, Agriculture Research Center (ARC),  
Benha  
Egypt  
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, North Africa

Dr Niwagaba Andrew Bakainaga  
WHO Country Advisor Uganda  
Kampala  
Uganda

Dr Jean Gitau  
Senior Officer  
Global Health Security, Ministry of Health  
Nairobi  
Kenya

Dr Atwiine Atek Kagirita  
Former Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa  
Kampala  
Uganda

Dr Kanana Kimonye  
Head  
Global Health Security, Ministry of Health  
Nairobi  
Kenya

Dr Esther Ngina Kisangau  
Country Readiness and IHR focal point for Kenya  
Emergency Preparedness and Response  
WHO Health Emergency programme  
WHO Country Office for Kenya  
Nairobi  
Kenya
Mr Jacques Maniriho
One Health Coordination Specialist
Ministry of Health
Kigali
Rwanda

Dr Donald I. Ofili (Rapporteur for session 2)
Director and Deputy Registrar
Medical Laboratory Science Council of Nigeria
Abuja
Nigeria
Chair, Regional Biosafety and Biosecurity Technical Working Group for West Africa

Mr Alex Owusu-Biney (Facilitator)
Portfolio Manager, Biosafety
GEF Coordination, Ecosystems Division
UNEP
Nairobi
Kenya

Mr Kwamena Essilfie Quaison
Director of the Science, Technology and Innovation
Directorate of the Ministry of the Ministry of Environment, Science, Technology and Innovation (MESTI)
Accra
Ghana

Dr Anna Laura Ross (Facilitator)
Unit Head
Emerging Technologies, Research Prioritisation and Support Research for Health Science Division
WHO headquarters
Geneva
Switzerland

Mr Dominic Twesigomwe
Director
National Counter Terrorism Center
Kampala
Uganda
Group work session 3

Group work A

Dr Soufiana Kaba (Rapporteur)
Coordonnateur du Projet d’Amélioration de la Santé Animale et de l’Hygiène Publique Vétérinaire (PASA-HPV)
Ministère des Ressources Animales et Halieutiques
Abidjan
Côte d’Ivoire

Dr Georges Alain Etoundi Mballa
Directeur de la Lutte contre la Maladie, les Epidémies et les Pandémies
Ministère de la Santé
Yaoundé
Cameroun

Professeure Josephine Ngo Mbing Epse Pegnyemb
Chef de la Cellule de la Promotion de la Recherche et de Développement des Pharmacopées Traditionnelles
Ministère de la Santé
Yaoundé
Cameroun

Mme Eugénie Molengo Mokombo
Chef de Bureau en charge des Institutions Humanitaires, Sociales et de l’Organisation Mondiale de la Santé (OMS) à la Direction des Organisation Internationales
Ministère des Affaires Etrangères
Kinshasa
République démocratique du Congo

Mr Gilbert Ahoka Tambeke
Chargé d’Etudes en charge des Questions de Santé au Cabinet du Vice-Premier Ministre
Ministère des Affaires Etrangères
Kinshasa
République démocratique du Congo

Professeur Gnomblessom Georges Tiahou
Sous-Directeur de la recherche
Ministère de la Santé de l’Hygiène Publique et de la Couverture Maladie Universelle
Abidjan
Côte d’Ivoire
Professeur Dieudonné Nyembue Tshipukane
Directeur Général de l’Institut de Recherche en Sciences de la Santé
Ministère de la recherche scientifique et innovation technologique
Kinshasa
République démocratique du Congo

Dr Soatiana Cathycia Rajatonirina (Facilitator)
Technical Officer
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division
WHO headquarters
Geneva
Switzerland

Dr Yro Hyacinthe Tie
Directeur de la Qualité de l’Environnement et de la Prévention des Risques
Ministère de l’Environnement et du Développement Durable
Abidjan
Côte d’Ivoire

Dr Anne Cécile Zoung-Kanyi Epse Bissek (Chair)
Chef de la Division de la Recherche Opérationnelle en Santé
Ministère de la Santé
Yaoundé
Cameroun

**Group work B**

Dr Jean Gitau
Senior Officer
Global Health Security, Ministry of Health
Nairobi
Kenya

Dr Kanana Kimonye (Rapporteur)
Head
Global Health Security, Ministry of Health
Nairobi
Kenya

Mr Jacques Maniriho
One Health Coordination Specialist
Ministry of Health
Kigali
Rwanda
Mr Charles Muitherero  
Data Manager  
WHO Country Office for Kenya  
Nairobi  
Kenya

Dr Abraham Oduro  
Director for Research and Development  
Ghana Health Service  
Accra  
Ghana

Mr Kwamena Essilfie Quaison  
Director of the Science, Technology and Innovation  
Directorate of the Ministry of the Ministry of Environment, Science, Technology and Innovation (MESTI)  
Accra  
Ghana

Dr Erigene Rutayisire  
Senior Lecturer of Public Health School of Public Health  
Kigali  
Rwanda

Mr Roland Taremwa  
Program Specialist, Monitoring and Evaluation  
Office of the Prime Minister  
Kampala  
Uganda

Dr Emmanuelle Tuerlings (Facilitator)  
Technical Officer  
Emerging Technologies, Research Prioritisation and Support Research for Health, Science Division  
WHO headquarters  
Geneva  
Switzerland

Mr Emmanuel Turyatunga (Chair)  
Assistant Commissioner, Monitoring and Evaluation  
Office of the Prime Minister  
Kampala  
Uganda
Mr Dominic Twesigomwe
Director
National Counter Terrorism Center
Kampala
Uganda
Annex 3. Meeting of partners

Dr Ali Asy
Professor of Pharmacology
Animal Health Research Institute, Agriculture Research Center (ARC)
Benha
Egypt
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, North Africa

Dr Niwagaba Andrew Bakainaga
WHO Country Advisor Uganda
Kampala
Uganda

Dr Atwiine Atek Kagirita
Former Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa
Kampala
Uganda

Mr Joshua Kimutai
Regional Laboratory Specialist
FAO
Nairobi
Kenya

Dr Esther Ngina Kisangau
Country Readiness and IHR focal point for Kenya
Emergency Preparedness and Response
WHO Health Emergency programme
WHO Country Office for Kenya
Nairobi
Kenya

Mr Mabusetsa Joseph Makalo
Senior Laboratory Technologist, Lesotho Central Veterinary Laboratory
Department of Livestock Services
Maseru
Lesotho
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, Southern Africa

Dr Dan Mogaka
Monitoring and Evaluation Officer and One Health Catalyst
Great Horn of Africa Food insecurity and Health Unit
WHO Health Emergency Programme
WHO Country Office for Somalia
Dr Joseph Chukwudi Okeibunor
Lead
Research, Development and Innovations team (including Digital Health)
Assistant Regional Director Cluster
WHO Regional Office for Africa
Brazzaville
Congo

Dr Donald I. Ofili
Director and Deputy Registrar
Medical Laboratory Science Council of Nigeria
Abuja
Nigeria
Chair, Regional Biosafety and Biosecurity Technical Working Group for West Africa

Mr Alex Owusu-Biney
Portfolio Manager Biosafety, GEF Coordination, Ecosystems Division
UNEP
Nairobi
Kenya

Dr Anna Laura Ross (Moderator)
Unit Head
Emerging Technologies, Research Prioritisation and Support Research for Health
Science Division
WHO headquarters
Geneva
Switzerland

Dr Samuel Wakhusama
WOAH Sub-Regional Representative for Eastern Africa
Nairobi
Kenya

Dr Kennedy Yatich (Rapporteur)
Chair, Regional Biosafety and Biosecurity Technical Working Group Africa CDC, East Africa
Nairobi
Kenya