

NATIONAL INVENTORIES OF DANGEROUS PATHOGENS EXPERT WORKSHOPS AND MANUAL DEVELOPMENT FOR INTER-REGIONAL IMPLEMENTATION

1. PROJECT ABSTRACT

The concept of biosecurity is an issue of international concern, and was given a new impetus after the 2001 anthrax letters in the United States. An effective countermeasure against biosecurity threats is ensuring that biological materials are secured from unauthorized access, and stored in a minimal number of facilities per country. However, though governments are responsible for securing dangerous pathogens against misuse, they would first need to know what pathogens are stored where in their country. A **National Inventory of Dangerous Pathogens**, an electronic database, provides a comprehensive overview of all laboratories in a country that work with pathogens of concern, and has proven to be successful in enhancing a countries' biosecurity capability. However, such an overview system is still not in place in many countries. Therefore, large-scale implementation of individual National Inventories would in this regard remedy a significant biosecurity gap for countries within this GHSA framework. To increase the number of countries having an operational and accurate National Inventory of Dangerous Pathogens, our project team aims to develop an '**Instrument for implementing a National Inventory**' that facilitates a systematic stand-alone approach for countries to set up their own National Inventory, thereby adhering to targets in the GHSA and WHO JEE, and the broader BTWC resolutions.

2. PROJECT PARTNERS

Project Partner	Institution, Department	Email address	Type of entity
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3. PROJECT TEAM

The project team consists of three biosafety and biosecurity experts from different, with all experts originate from different sectors; Medical research institute (KEMRI)/ African Biosafety Association (AfBSA), Tanzania Veterinary Laboratory and a National Institute of Public Health. Among the participants, one is IFBA certified in biorisk-management, and two members of the project team are part of the GHSA Next Generation Network as well as members of the GHSA Action Package on Biosafety and Biosecurity. Considering that currently a National Inventory of Dangerous Pathogens is being implemented in Kenya, the constellation of the project team can closely follow the developments in Kenya and use this experience develop best practises. Additionally, the project team can already meet during the announced biosecurity conference in Nairobi in March in 2018, potentially consulting additional key experts.

4. PROJECT BACKGROUND

Emerging and re-emerging diseases pose a significant burden on global public health. To combat the threat of infectious diseases, research with dangerous pathogens is conducted in laboratories around the world to develop novel drugs, diagnostics and vaccines. At the same time, laboratories dedicated to work with dangerous biological materials are also possible targets for sabotage or

theft by non-state actors. This threat was highlighted after letters with powdered *Bacillus anthracis* were sent to American news media and government offices in 2001. Due to this incident the concept of biosecurity was given a new impetus, and resulted in novel policies in order to secure dangerous pathogens against deliberate misuse. An effective countermeasure against biosecurity threats is ensuring that biological materials are secured from unauthorized access, in a minimal number of facilities per country. For this, governments would first need to know what pathogens are stored where in their countries.

A **National Inventory of Dangerous Pathogens** is an electronic database, which provides a comprehensive overview of all laboratories that work with pathogens of concern, but also laboratories that use genetic engineering with dual-use potential. Signatory state parties are required to comply with the regulations of the Biological Toxins and Weapons Convention (BTWC), and these regulations deal with the safety and security of dangerous biological agents or toxins in laboratories to prevent unauthorized access to such agents or toxins for misuse. The availability of a National Inventory of Dangerous Pathogens would enable a government to develop regulations to enhance biosecurity measures and specify policy to mitigate biosecurity risks. In addition, this inventory would act as a tool to develop, or further specify regulation- and certification systems for laboratories that work with pathogens of concern or conduct dual-use research. In addition, such an overview would strengthen biopreparedness in terms of capacity to prevent, detect and respond to both accidents and deliberate misuse of biological agents.

Within the framework of the GHSA, a key aim is to ensure a whole-of-government national biosafety and biosecurity system is in place, safeguarding that especially dangerous pathogens are identified, held, secured and monitored in a minimal number of facilities according to best practices. A National Inventory, which was previously piloted in the Republic of Uganda, has recently been recognized by the WHO JEE evaluation to have aided in a developed capacity concerning biosafety and biosecurity. However, such an overview system is still not in place in many countries, as at least 26 out of 38 countries were recommended by the WHO JEE to prioritize the development of a National Inventory in their country. Therefore, a National Inventory would remedy a significant biosecurity gap for many countries within the GHSA framework. To increase the number of countries with their own operational and accurate National Inventory, the project team proposes to develop an '**Instrument for Implementing a National Inventory**'. This instrument will facilitate a systematic stand-alone approach for countries to set up their own National Inventory. This in turn would bring us one step closer to addressing the existing biosecurity gap and enhancing regional capability to achieve the biological security targets within the GHSA and JEE.

5. WORKPLAN

a) Main objective

The overall aim of this project is to increase the number of countries having an operational and accurate National Inventory of Dangerous Pathogens, by large-scale implementation of individual National Inventories by State Parties. Therefore, our project team proposes to develop an '**Instrument for implementing a National Inventory**' (Figure 1). This instrument would facilitate a systematic stand-alone approach for countries to set up their own National Inventory.

Therefore, the objectives are:

- I. To obtain commitment from national entities responsible for BTWC implementation;
- II. To develop a standardized manual with dedicated software, that provides a systematic approach on how to implement a National Inventory of Dangerous Pathogens;
- III. To establish a Next Generation Global Health Security Platform, existing of multi-sectoral experts (i.e. ICT experts, microbiologists, policy makers) to support countries with the implementation and maintenance of the database.

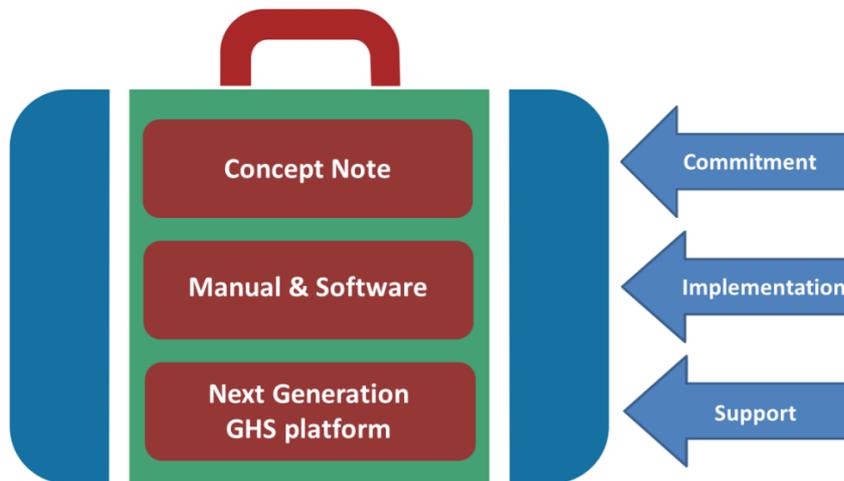


Figure 1: Our Instrument consists of a commitment phase an implementation phase and a support phase.

b) Approach

The different phases that are required to construct an 'Instrument for implementing a National Inventory' show how the project team will work within the GHSA network to integrate this instrument within existing frameworks to make the instrument becomes available for a great number of countries (fig. 2).

Preparatory meeting (Y1:Q1)

The project team will gather in a preparatory meeting in order to draft a roadmap. This roadmap will set out the scope of the project and align around key milestones over a three-year period. The roadmap will include an action plan, time frames, and communication plans.

Deliverable

* Roadmap with actions and action holders, time frame, and communication plans

Workshop with international experts (Y1:Q1-Q2)

The team of experts will meet during a seven-day workshop in order to share best practises regarding (large-scale) implementation of individual National Inventories. The workshop pursues to construct a concept note to promote commitment from national entities responsible for BTWC implementation, and to develop a standardized manual to guide countries on how to implement a National Inventory. The manual could be discussed during round table discussions with international experts, maybe as early as the APP3 biosafety and biosecurity meeting in Nairobi in 2018. For additional feedback, the manual can also be disseminated within the GHSA APP 3 of biosafety and biosecurity, in which two of three of this project team are member.

Deliverable

- * Concept note to obtain high level commitment for implementing a National Inventory
- * Harmonize on best practises which are to be included in the standardized manual
- * Standardized manual with the best practices on implementing a National Inventory

Exposure to relevant Stakeholders (Y1:Q3-Q4)

To raise more awareness concerning our novel instrument, our team of experts will present our project at different conferences with relevant stakeholders (i.e. BTWC-, WHO-, GHSA-, Centre of Excellence-, or global partnerships meetings). In addition, to maximize the impact we propose to publish a scientific paper and develop a promotion video.

Deliverables

- * Conference presentation to promote the 'Instrument for Implementation a National Inventory'
- * Video to promote the 'Instrument for Implementing a National Inventory'
- * Publication to explain the development process of the National Inventory of Pathogens

Establishment of Next Generation Platform (Y2-3:Q1-Q4)

Our project team will gauge possibilities to working within the Next Generation GHS Network in order to establish a novel platform of professionals across-sectors. Members of this platform can pilot our novel 'Instrument for Implementation' in a few countries, before its full-scale launch. Furthermore, the GHS platform is foreseen to act as a central point of contact to support countries with setting up their own National Inventory. This could for example, be achieved by establishing a Next Generation GHS forum for sharing ideas, questions and concerns. To maximize the impact of the instrument, we also intent to seek opportunities to integrate our 'Instrument for Implementation' in existing international frameworks, as it in compliance with targets in both the GHSA and WHO JEE.

Deliverables

- * Establishment of novel Next Generation GHS platform to promote large-scale implementation of individual National Inventories (i.e. website or GHS Next Gen forum)
- * Translation of the instrument to different languages (in kind from GHSA)
- * A consolidated and validated instrument integrated in existing framework



Figure 2: A schematic overview of timeframe and the different steps to achieve the long-term objective.

6. ESTIMATED BUDGET

We foresee an implementation budget of 80k\$, consisting of person months for the applicants (50k\$), for the workshop, attendance of 2018 Nairobi Biosecurity meeting (20k\$ travel and meeting subsistence), and attendance of BTWC and GHSA meeting for exposure of the tool (10k\$ travel and substance). We would petition for translation costs and website space as in kind contribution from the GHSA.

7. POTENTIAL RISKS

The National Inventory is a ready-to-use database, making customization difficult, though it allows for different types of entities. To make the standardized manual and dedicated software available for a wide range of countries, the manual will be translated in different languages. We hope that translation of the instrument could be facilitated in kind of the GHSA by in-house translators, or via the GHSA Next Generation Network. Entities might want to set up their own customized inventory, though the Next Generation GHS platform can still provide support and advice on use and implementation.