

Information Note¹

- Event:** WHO Consultative meeting on guidance for a biosafety and biosecurity regulatory framework
- Organizer:** World Health Organization
- Date and Venue:** 26-28 September 2018, World Health Organization
- Participants:** National officials, international organisations, a regional organisation, a global initiative

Background

On 29 August 2018, the Director of Country Health Emergency Preparedness and IHR in WHO's Health Emergencies Programme sent a letter to the Chair of the 1540 Committee inviting a representative to take part in the WHO Consultative meeting on guidance for a biosafety and biosecurity regulatory framework.

The objectives of the meeting were to present and discuss the current state of national biosafety and biosecurity regulatory frameworks; update a diversified global audience of stakeholders on the development and intent of the WHO Guidance document for the stepwise implementation of biosafety and biosecurity regulatory requirements and solicit feedback on the document in an effort to improve usability; discuss future dissemination and use of the WHO Guidance document for establishing or enhancing a biosafety and biosecurity regulatory framework particularly in resource-limited countries; and facilitate networking between Member States to encourage greater partnership on strengthening biosafety and biosecurity regulations.

Highlights

The first day started with opening remarks about the objectives of the meeting by WHO officials. They underlined that the document *Stepwise implementation of regulatory requirements for ensuring biosafety and biosecurity in biomedical laboratories* (hereinafter "WHO Guidance Document") was developed by WHO in response to a perceived lack of biosecurity regulations in place in countries around the world.

We heard presentations from each of WHO's regional offices: AMRO, EMRO, EURO, SEARO and WPRO about biosafety and biosecurity efforts in each of the respective regions they cover. We then heard presentations by FAO and IAEA and the World Animal Health Organisation, or OIE, on international standards for animal laboratory biosafety and biosecurity.

¹ For information – not an official report. The views expressed here do not necessarily represent those of the 1540 Committee or of the organisers or participants in the event.

The 1540 Expert next gave a basic introduction to resolution 1540 (2004), with statistics specific to non-proliferation of biological weapons and related materials. He then drew attention to operative paragraphs 12, 14 and 15 of resolution 2325 (2016), as well as particular attention to operative paragraphs 17 (effective implementation best practices), 23 (enhanced co-operation and information sharing with the 1540 Committee by international, regional and sub-regional organisations) and 25 (highlight the obligations of resolution 1540 (2004) in the model legislation and/or guidelines of international, regional and sub-regional organisations). He stressed that WHO and their consultants developing the WHO Guidance Document should consider highlighting the obligations of resolution 1540 (2004) throughout the document.

The final presentation in this set was on the initiative “Global Health Security Agenda” (GHSA), and in particular GHSA Action Package 3 on biosafety and biosecurity, with a focus on tools and training.

We then heard a presentation from a representative of the International Federation of Biosafety Associations (IFBA) and their work with Mali on improving their national regulatory framework for biosafety and biosecurity, which is a multi-year project funded by Global Affairs Canada.

The workshop then turned to national presentations—providing an opportunity for the 1540 Expert to identify effective implementation best practices for regulation of biosecurity—from Denmark, the European Union, Mexico, the Russian Federation and the United States.

After the first set of national presentations, the next section in the agenda was on countries in the world that plan to use the WHO Guidance Document to improve their biosecurity regulatory frameworks including the Caribbean Public Health Agency (CARPHA), Indonesia, Mongolia, and Viet Nam.

A speaker from Public Health Agency Canada gave a stand-alone presentation on their analytical approach (AA) to strengthening capacity for pathogen biosafety and biosecurity.

On the second day, a WHO official gave an overview of the forthcoming Laboratory Biosafety Manual, 4th Edition. The Manual does not include biosecurity concepts, which will be included in a separate monograph. New technologies, for example, CRISPR, will also be covered in a separate monograph. We then heard a presentation on the WHO Joint External Evaluation and its evolution.

This led the consultative meeting to the heart of the consultations, a presentation on the WHO Guidance Document. The scope of the WHO Guidance Document is mainly to support policy makers and regulators with an emphasis on an adequate regulatory framework. The participants learned that the WHO Guidance Document was piloted in Ethiopia.

The final presentation before the participants were broken into groups was on the eight major steps of the stepwise approach to regulating biomedical laboratory biosafety and biosecurity. These steps are: set up national policies and strategies for biosafety and biosecurity; conduct a national evaluation and survey of existing legislation and regulatory framework for biosafety and biosecurity; perform biosafety and biosecurity capacity-building to design and implement a

regulatory system; establish national institutions for biosafety and biosecurity; develop best-fitting regulations; implement the regulations; establish national information exchange and international collaboration on regulating biosafety and biosecurity; and review performance and adaptability to national context and risks.

The participants then broke into two groups. The objective was for each group to go through the eight steps of the stepwise implementation of regulatory requirements for ensuring biosafety and biosecurity in biomedical laboratories. Among the outcomes of the Group Work, the consultants developing the WHO Guidance Document agreed that the obligations arising under resolution 1540 (2004) should be highlighted throughout the document along with reference to other multisectoral approaches including OIE's biothreat strategy and the BWC.

Additional Comments

For further information, please contact the 1540 Committee experts by e-mail at 1540experts@un.org.