Questions and Answers Session

MX3 Webinar

Kenya

Mary Onsarigo:

1. **Many NCPs faced the issue of lack of authority when coordinating with other ministries or collecting data related to CBMs. How did NACOSTI overcome these difficulties?**

   "NACOSTI's mandate and authority comes from the Act which allows collection of any information regarding Science Technology and Innovation from all research organizations, universities, and departments of different ministries. It is a national authority that regulates research in the country. It also clears all research by issuing research permits to both National and International researchers."

2. **We have many questions related to challenges faced by NACOSTI:**
   a. **Can you please expand more on institutional challenges NACOSTI has faced? And what steps did you take to overcome them?**

      "Most institutions did not respond to NACOSTI's request for information on CBM. NACOSTI request information by sending official letters to the heads of institution to provide the relevant information. Previously, very few institutions responded positively especially those who had participated in an activity related to BWC. We have slightly improved on getting information from more institutions through awareness creation and sensitization workshops. The challenge is still existing because not all institutions have been sensitized on issues of Biosecurity. This will be a continuous process to improve on information collection."

   b. **What are the main challenges your government faced when establishing NACOSTI? Which ministry was first involved in the creation process?**

      "Kenya Acceded to the convention in 1976. This remained in the ministry of foreign affairs since by default is the custodian of all conventions and treaties which Kenya has acceded to or ratified. For 34 years CBMs were never submitted. This was because CBMs required expertise in Science technology and Innovation who may not be in the Ministry of Foreign Affairs. It took the scientists who attended a BWC meeting in 2008 and come back with a report and recommended that the right place as a Focal Point for the convention was in an institution that advises the government on matters of Science and Technology. At that time, the Ministry of Education, Science and Technology, then identified National Council for Science and Technology (NCST) which was a semi-Autonomous Agency as the

right institution. NCST advised the government in matters of science and technology. This was a mandate given by the S&T Act of 1977. When this Act was revised in 2013, NCST was elevated to a commission which is the National Commission for Science Technology and Innovation (NACOSTI). The Mandate was expanded and remained to be the Focal Point of BWC. NACOSTI is the institution under the ministry of education that regulates Research and clears all research by issuing research permits in the country."

c. How are you addressing the challenges you presented (raising awareness, scientists fear of losing business due to information sharing, etc)

"This requires a lot of awareness creation and assurance to the scientific community to understand Article X of the convention (Undertaking to facilitate, and right to participate in, the fullest possible exchange of equipment, materials, and information for peaceful purposes). Awareness emphasises that the convention does not hinder them from doing research. Instead, it encourages discovery of new knowledge and development of new skills as long as it is for peaceful purposes. NACOSTI is in addition sensitizing the scientific community and researchers on intellectual property Rights and Patents. This will allow them to protect their innovative ideas before declaring the research they are undertaking."

UK (jointly with Sweden and Switzerland)

Amber Murch:

1. **Your proposal implies strong collaboration between two or many States on the identification of relevant vaccine production facilities that may be missed under the current CBM G wording, how would States overcome potential divergence of view related to differences in their domestic legislations?**

"The UK would encourage States Parties to adopt an approach to CBMs, including the reporting of vaccine production facilities under CBM G that is as transparent as possible. Domestic legislation may differ between States Parties, therefore this highlights the importance of collaboration and sharing best practice in reporting for CBMs. As mentioned in the presentation the UK is very happy to share reporting practices for CBM G."

2. **Stakeholders from the private sector play a crucial part in sharing data related to vaccines, how does such a proposal impact on their work?**

"Absolutely agreed, the private sector plays a key role in transparency relating to CBMs. The reporting of commercial vaccine production facilities should be detailed enough to highlight the work done at the

facility, showing how it meets the broad interpretation of CBM G declarations. However, stakeholders may share appropriate information as requested by the State, while choosing not to disclose sensitive information, such as client names or detailed information relating to intellectual property."

Africa CDC

Talkmore Maruta:

1. Based on your experience supporting many African States, what are the main challenges when transiting from the development phase of a Biosafety and Biosecurity Legal Framework and effectively adopting them into domestic legislations?

   "Process of ratification, adoption and inclusion or coming up with national legislation is very long, running into several years in some instances. This maybe due to lack of understanding of the legal instruments proposed, poor advocacy and communication ahead of domestication. Lack of coordination of the process of domestication. Biosafety and Biosecurity cuts across many disciplines, departments and ministries – coordinating all stakeholders is challenging. Lack of or limited expertise in development of legal instruments for biosafety and biosecurity in Member States."

2. BWC National Contact Points play an instrumental role in coordinating BWC national implementation with all relevant agencies. What is Africa CDC current interaction with BWC National Contact Points?

   "The Biosafety and Biosecurity Initiative was launched in 2019 and was capacitated with staff in 2020. As evidenced by the involvement in this meeting of Africa CDC, important key first steps for collaboration are being taken. There is currently interaction with BWC team including sharing of Africa CDC 5 Years Strategic Plan (2021-2025). The BWC Implementation Support Team reviewed the Regional Biosafety and Biosecurity Legal Framework currently in development and they participated in the regional consultations for the framework."

NTI/WEF

Dr. Jaime Yassif, Ms. Elissa Prichep and Dr. Nicole Wheeler:

1. You mentioned that in 2020, NTI and WEF released a report on "Biosecurity Innovation and Risk Reduction", and it has been prepared by an expert Working Group, from global public and private sector. Could you give more information on the composition of that working group and its selection process?

> "Members of the Working Group were invited based on technical expertise as well as international and cross-sectoral representation to ensure a diversity of perspectives."

2. **Do you have a sense of how many cases have been picked up by the consortium thus far;**
   a. **What is the follow-up enforcement process beyond flagging and logging cases (as far as you can talk about this)?**
   b. **What incentives are currently considered?**

> "The Technical Consortium is currently developing and preparing to prototype a tool for screening, so we have not caught anything yet. Also, to clarify, we are developing an international Common Mechanism that companies will use, so we expect companies to catch issues in the future, not the Consortium. DNA providers who currently screen report that approximately 1% of their orders are for pathogen or toxin DNA, and the vast majority are for legitimate research uses. In very rare cases, DNA providers may want to report a suspicious order to the appropriate authority to follow up. In the U.S., there are contacts at the FBI WMD Directorate, who can address such cases. (The U.S. Department of Health and Human Services Screening Framework Guidance directs DNA providers to the FBI WMD Directorate for this purpose.) In other parts of the world, including Europe, there is less clarity about which authority should be contacted.
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> When a flag is raised based on the DNA sequence in an order, a DNA provider should check with the customer to determine whether they have a legitimate use for the requested materials. While this may sound simple, it is one of the most challenging aspects of this work.
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> The current incentives we are considering to encourage use of the Common Mechanism include: ensuring the Common Mechanism is low cost and easy to use; providing additional resources for users (e.g. export control or customer screening decision support tools); ensuring additional legitimacy with a "seal of approval" for users; and working with partners to develop and promote financial or regulatory incentives. We are certainly open to suggestions and ideas on additional incentives."