Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Biological risk assessment and management

Biological risk assessment and management: a need for guiding principles and frameworks

Submitted by the United Kingdom of Great Britain and Northern Ireland

I. Introduction

1. Biological risk assessment and management has been identified as a topic on which there is potential to move forward on practical and institutional issues within the scope and mandate of the current ISP[1]. Some States Parties have highlighted the need to develop broad guiding principles for biological risk assessment and management on issues specific to the Convention, which could be adapted to national circumstances.[2]

2. During the current ISP, several States Parties have submitted Working Papers that mention a role for principles, tools, methodologies or frameworks to help analyse the potential risks and benefits from developments in science and technology relevant to the Convention, and there have been some fruitful discussions, including on some examples of such principles and frameworks. As we prepare for the Ninth Review Conference and consider proposals for a new systematic and structured science and technology review process, it will be important to also consider the approaches required to focus attention on the most relevant developments and achieve an optimal outcome on assessing and managing both benefits and risks. The UK WP submitted to the 2019 MX2 concluded that it would be beneficial to have in place some guiding principles, tools or frameworks that could be used for risk assessment and management during the work of the next ISP.[3] We also recommended

[1] Meeting of Experts on Review of Developments in the Field of Science and Technology Related to the Convention: Reflections and proposals for possible outcomes. Submitted by the Chair of the Meeting of Experts on Review of Developments in the Field of Science and Technology Related to the Convention. BWC/MSP/2018/CRP.3

[2] Report of the 2019 Meeting of Experts on review of developments in the field of science and technology related to the Convention: Annex I Summary report. Submitted by the Chairperson of the Meeting of Experts on review of Developments in the Field of Science and Technology Related to the Convention. BWC/MSP/2019/MX.2/2

[3] Biological risk assessment and management: some further considerations. Submitted by the United Kingdom of Great Britain and Northern Ireland. BWC/MSP/2019/MX.2/WP.6

that MX2 explore the applicability of some available frameworks and principles in the context of the BTWC to assess the requirements and possible tools.

II. IAP Pilot Exercise Using Qualitative Frameworks

3. One type of approach for benefit and risk assessment and management involves the application of qualitative frameworks. In August 2019, the IAP and the US National Academies convened a meeting to pilot the use of two qualitative frameworks that had been developed previously to assess security concerns. Participants with a range of expertise across the life sciences and chemistry, public health, and science and security policy, from 17 countries and 3 international organisations, worked through a group process using these frameworks to assess two hypothetical case examples representative of the types of scientific developments discussed in BTWC meetings. The groups reached similar conclusions on the implications and potential concerns relating to the case studies using each of the frameworks. The project concluded that qualitative frameworks have features that make them suitable as tools to foster systematic discussions, show areas of agreement and disagreement, and provide a basis for continuing dialogue. Such frameworks enable security risks to be assessed in a systematic manner and provide evidence-based outcomes to inform policymakers.[4]

4. The project also explored how to approach the development of a framework to enable structured discussions on the positive implications of scientific developments for the BTWC and how to balance such benefits with the mitigation of potential risks. Although there are several approaches available to assess the risks of such developments, there is currently nothing comparable to assess the potential benefits for the implementation of the Convention. Initial discussion focussed on some of the elements that might be part of a qualitative framework that incudes benefits assessment. These were preliminary discussions and much work remains to be done in this area. However, it was concluded that it would be preferable for any qualitative framework used or developed in the BTWC context to evaluate both risks and benefits, and to include a process to balance measures to address them.

5. Using this framework approach also revealed the value of a group process to analyse case studies. Structured discussions allowed differences in interpretation to be identified and addressed, including those resulting from language and cultural differences, and highlighted key aspects of importance in developing or adapting a pre-existing network for BTWC purposes. For example, key contributors need to be involved at the outset to determine how the framework should be tailored to meet requirements, including by adapting terminology and assessment elements to ensure clarity and understanding in the BTWC arena. This would likely include both technical experts, from both governmental and non-governmental communities, to provide scientific expertise for the technical assessment elements, and policymakers for consideration of governance and policy options. In this exercise, participants from a range of countries and disciplines applied the frameworks successfully, suggesting that such approaches could be applicable in a wider setting such as the BTWC science and technology review process.

III. Other approaches

6. The frameworks described in the previous section provide some material for MX2 to discuss and examine potential applicability in the context of the BTWC. However, a wider assessment of possible principles, tools and frameworks will be required to identify and develop the most suitable methodologies; thus opportunities to trial other approaches would be useful. Some available tools focus mainly on the assessment and understanding of potential risks, though some also mention the importance of considering benefits. This area requires specific attention in the BTWC context; in particular to achieve a balance between realising the benefits of scientific developments and mitigating potential risks. Some tools

[4] Assessing the Potential Biosecurity Risks and Benefits of Advances in Science and Technology: Results of a Pilot Exercise Using Qualitative Frameworks. The InterAcademy Partnership 2019 https://www.interacademies.org/publication/assessing-biosecurity-risks-and-potential-benefits-advances-science-and-technology

also include an element of assessing risk management options, including potential governance measures. However, a set of guiding principles may be particularly appropriate in the context of governance related to BTWC obligations. This could allow States Parties to assess the range of possible governance measures and select those appropriate to develop a framework for their national circumstances. The recent US Working Paper[5] provides a more detailed discussion of approaches to governance for scientific and technological developments of relevance to the Convention and provides a good basis for further expert discussion in MX2.

7. The UK 2018 MX2 Working Paper[6] provided some ideas on how to structure deliberations on biological risk assessment and management of the potential impact of scientific and technological developments, including consideration of the balance between benefits and risks. These were divided under the headings 'What are we concerned about?', 'How should we assess the risks', and 'How should we manage the risks?'. The range of questions posed under each heading, and some additional factors presented in the UK 2019 MX2 Working Paper[7] can be drawn on in the development of guiding principles, frameworks or other practical approaches to achieve balanced assessments of benefits and risks, and to apply suitable and proportional mitigation measures.

IV. Conclusions and recommendations

8. During the remaining MX2 activities of the current ISP, we recommend that experts make concerted efforts to advance discussions on biological risk assessment and management and aim to provide some clear recommendations to the Ninth Review Conference and for future work. Whatever form of scientific and technological review process emerges from the Review Conference will benefit greatly from the ability to utilise some guiding principles, tools or frameworks in its activities. A key initial task for a new systematic and structured process might be to identify and develop appropriate methodologies. To make the best of use of the scientific and technological review process, it will be important to ensure useful and relevant output from risk assessment and management activities. This should include the ability to provide recommendations for consideration at subsequent meetings of SPs, which can make decisions on collective or individual measures to help exploit the benefits and manage potential risks of scientific and technological developments relevant to the BTWC.

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[5] Approaches to Governance for Scientific and Technological Advances in the Life Sciences Relevant to the Biological and Toxin Weapons Convention. Submitted by the United States of America. BWC//MSP/2020/MX.2/WP.1

[6] Genome editing: addressing implications for the Biological and Toxin Weapons Convention. Submitted by the United Kingdom of Great Britain and Northern Ireland. BWC/MSP/2018/MX.2/WP.4

[7] Biological risk assessment and management: some further considerations. Submitted by the United Kingdom of Great Britain and Northern Ireland. BWC/MSP/2019/MX.2/WP.6