

**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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Item 5 of the provisional agenda

Biological risk assessment and management

**Biological risk assessment and management: some further
considerations**

**Submitted by the United Kingdom of Great Britain and Northern
Ireland**

I. Introduction

1. The UK Working Paper submitted to the 2018 MX2 addressed the potential consequences of advances in genome editing for the Convention, focussing on the specific elements on the MX2 agenda.¹ In particular, it aimed to identify some topics and questions to stimulate expert discussions in MX2 on the opportunities and challenges emerging, and on the actions that States Parties could consider, individually and collectively, to address them. The biological risk management and assessment section offered some specific questions to facilitate deliberations on genome editing, and potentially on the impact of other scientific and technological advances, including consideration of the balance between benefits and risks.

2. The 2018 MX2 featured fruitful discussions on the requirements and methodologies for biological risk assessment and management. Several States Parties made contributions that highlighted the importance of these aspects and a willingness to continue trying to identify possible harmonized approaches. Some examples were provided of the type of guiding principles and tools, such as qualitative frameworks, that could be considered. The paper submitted to the 2018 MSP by the MX2 Chair, offering his reflections and proposals for possible outcomes, recognised that a sizeable part of the discussions was dedicated to ethical and regulatory issues. The Chair's paper proposed that further activities during the current ISP should explore areas that had achieved greater commonality of approaches: biological risk assessment and management, and development of a voluntary model code of

¹ 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.



conduct.² This Working Paper provides some additional factors to consider in MX2 discussions on practical approaches to achieve balanced assessments of benefits and risks, and to apply suitable and proportional mitigation measures.

II. What are we concerned about?

3. In WP.4 to last year's MX2, we focussed our questions largely on technical advances in the field of genome editing, with some consideration of related genetic technologies and synergistic technologies, such as production and delivery systems. However, in developing approaches to address this aspect of risk assessment, it would be useful for States Parties to consider scientific and technological advances in different areas to ensure that principles and frameworks are adaptable. Furthermore, in any such considerations it is crucial to weigh the potential benefits of advances against the assessed risks. Hence, in the early stages of assessment we need also to identify the realistic potential benefits, which will allow a more balanced assessment by methodologies considered under the question 'How should we assess the risks?'

4. Many well-publicised advances in biotechnology fall into the category of 'enabling technologies', which can be broadly applied in many areas. It can also be difficult to predict the full potential in the early stages of emerging technologies and to analyse the risks and benefits across the wide spectrum of activities. Thus, it may be more useful to focus on specific applications of the enabling technologies when considering areas of concern, while maintaining a technology watch to identify stages of development that might indicate a need for further assessment.

5. Other aspects related to advances in relevant technical fields may also be worth consideration in assessing what is of concern. The convergence of technologies from traditionally different fields may bring together communities of scientists from a variety of disciplines, such as the physical sciences, engineering and information technology, who may be less familiar with the potential risks in the field of biology. The burgeoning interest in citizen science/DIY biology may also result in communities with less awareness of the risks, which are outside the established professional scientific umbrella. Advances in information technology have increased the availability and accessibility of information, which could increase its potential for misuse in a context relevant to the Convention. Intangible technology is also a key factor to take into account. Hence, we must think beyond the technical capabilities and look at the wider impacts associated with developments in science and technology when assessing the risks; it may be several factors coming together at an appropriate time that would raise concerns.

III. How should we assess the risks?

6. Some examples of risk assessment approaches were discussed at last year's MX2. It was noted that these were generally focussed on the assessment of risk and did not tend to include an integral evaluation of potential benefits of advances. Thus, although such approaches could allow examination of the implications of the technologies for the BTWC in the context of their potential misuse, a side-by-side assessment of potential benefits would be required to provide a balanced picture. The determination of what levels of risk are acceptable would also be useful. Consideration of who should be involved in predicting the implications is of significant importance, particularly given the potential for involvement of wider communities in relevant scientific and technological areas, the need to balance benefits and risks, and the potential societal implications.

7. More detailed discussion of approaches to the assessment of benefits and risks from scientific and technological developments of relevance to the Convention can be found in the

² 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

recent Swiss and US Working Papers;³ these provide a good basis from which to continue expert discussions in MX2. States Parties should carry out some evaluation of available risk and benefit assessment frameworks to determine their suitability for use in the BTWC context, or to assist the development of relevant guiding principles or frameworks for future use. The output from recent or planned workshops and events may provide appropriate material to facilitate this.⁴ Looking at case studies from previous examples of controversial research could also help to understand both their implications for the Convention and their subsequent benefits for peaceful purposes, including public health and agriculture.⁵

IV. How should we manage the risks?

8. The range of governance measures available to address and mitigate the potential security risks from advances in science and technology has had much discussion in BTWC meetings and elsewhere. Some recent workshops and events addressed governance measures further, either in a general context or focussed on specific technologies.⁶ The output of these and other relevant events could provide valuable material for future discussion on risk management in MX2.

9. The 2018 UK WP.4 outlined a range of governance measures that could be appropriate to mitigate potential security risks. These included legislation, regulations, guidelines, standards, funder reviews and oversight, codes of conduct, education, and self-governance. States Parties have observed that the optimum combination of such measures may differ depending on national circumstances; a one-size-fits-all model is unlikely to be the solution. Thus, some guidance and models to assist development of appropriate governance frameworks could be helpful. As well as having a governance framework in place, it is important to have a strategy for implementation of the relevant measures; this requires awareness of the issues and interaction among all the sectors and communities involved. We must look to build trust and confidence in the design and application of a governance framework. These issues are also relevant to our discussions in MX3 on strengthening national implementation.

10. There are also practical and technical measures that can be applied to reduce the risk. The development of countermeasures, such as detection methods and prophylactic and therapeutic measures, to address the risks posed could be a factor in deterring the misuse of technologies. Technical measures could be applied to prevent or reduce the potential for inadvertent or deliberate harm from the products of life sciences research. For example, in genetic modification experiments it is possible to introduce conditional lethal genetic switches that will prevent the genetically modified organisms from surviving outside controlled laboratory containment conditions. Biosafety and biosecurity measures and

3. Scientific and Technological Developments of Relevance to the Convention and the Assessment of Benefits and Risks. Submitted by Switzerland BWC/MSP/2019/MX.2/WP.2*.

Approaches to Risk and Benefit Assessment for Advances in the Life Sciences. Submitted by the United States of America. BWC/MSP/2019/MX.2/WP.3.

4 For example, the InterAcademy Partnership and US National Academies of Science, Engineering and Medicine workshop on 'Qualitative Frameworks to Assess Risks and Benefits of Advances in Science and Technology: Opportunities for the BWC'. Geneva 1 August 2019.

5 For example, see Taubenberger JK et al (2012) Reconstruction of the 1918 Influenza Virus: Unexpected Rewards from the Past. *mBio* 3(5):e00201-12, which gives a specific example of subsequent public health benefits from an area of dual use research.

6 Assessing the Security Implications of Genome Editing Technology. Report of an international workshop, Herrenhausen, Germany 11-13 October 2017. Convened by the IAP, the European Academies' Sciences Advisory Council (EASAC), the US National Academies of Science, Engineering and Medicine (NASEM), and the German National Academy of Sciences Leopoldina. Security for Emerging Synthetic Biology and Biotechnology Threats. NATO Science for Peace and Security Programme Advanced Research Workshop. Lausanne, Switzerland, 7-10 July 2019. Novel Practices of Biosecurity Governance. University of Cambridge Centre for the Study of Existential Risk, 11-13 July 2019.

practices themselves play a role in preventing inadvertent or deliberate release of harmful biological materials, contributing to the safe and secure conduct of science.

V. Conclusions and recommendations

11. 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.⁷ Concerted efforts in MX2 may produce some clear recommendations for the Ninth Review Conference and for future work. Some States Parties have already begun to propose ideas on the nature of future scientific and technological review processes.⁸ The United Kingdom believes that it would be beneficial to have in place some guiding principles, tools or frameworks for biological risk assessment and management that could be used during the work of the next ISP.

12. We would therefore recommend that, in the remaining time of the ISP, MX2 explores the applicability of some available frameworks and principles in the context of the BTWC to assess the requirements and possible tools. There will also be relevant materials from academic initiatives that can add to such deliberations. There are many recent advances in science and technology that could serve as case studies in evaluating the suitability of assessment methodologies. We think that it would be preferable to examine more than one example. Some possible topics are included in the recent Swiss WP.2 and in the UK WP.17 submitted to the Eighth Review Conference,⁹ as well as in other papers and presentations.

⁷ 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.

⁸ Rethinking the BTWC science and technology review: A renewed case for a BTWC Scientific and Technological Experts Advisory Forum (STEAF). Submitted by Germany, co-sponsored by the Netherlands and Sweden. BWC/MSP/2019/MX.2/WP.1.

⁹ Review of Developments in Science and Technology: Key Points from the 2012-2015 Biological and Toxin Weapons Convention Intersessional Programme. Submitted by the United Kingdom of Great Britain and Northern Ireland. BWC/CONF.VIII/WP.17