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SCIENCE HEALTH POLICY

Assessing the

Potential Biosecurity Risks and Benefits of Advances in Science and Technology:

Results of a Pilot Exercise Using Qualitative Frameworks

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Summary

Understanding the potential implications of advances in science and technology (S&T) for the operation of the Biological Weapons Convention (BWC) is a key task for the Convention[I]. The lack of a commonly accepted method for assessing relevant risks presents significant challenges, however. In addition, a framework to assess the potential benefits arising from S&T could similarly inform the Convention. Qualitative frameworks have features that make them amenable to serving as tools to foster systematic discussions, reveal areas of agreement and disagreement, and provide a basis for continuing dialogue.

The InterAcademy Partnership (IAP) and the US National Academies of Sciences, Engineering, and Medicine collaborated on a pilot exercise to examine how two qualitative frameworks could facilitate structured discussions of advances in S&T using BWC-relevant case examples. In a pilot exercise on 1 August 2019, participants worked through these frameworks and discussed areas in which they could be adapted to help support the BWC.

I Article XII of the BWC calls for regular reviews to "...take into account any new scientific and technological developments relevant to the Convention."

Background

A number of approaches are available to assess the potential risks of advances in S&T, from formal quantitative risk assessment models through varied data analytic approaches to qualitative tools[I]. All such approaches can potentially contribute to evaluation of S&T impacts for the BWC in particular ways, such as in national or collective assessments made by States Parties or in the work of civil society. This project focused on the development of a qualitative framework that could structure and guide systematic discussions among experts. A key feature of the approach was the use of a group process, with collective discussions of potential risks and benefits.

In this context, a "framework" can be defined simply as a mental model or a structured way to think about a problem. Such a framework provides a list of decision criteria that are a shared representation of expert thinking on an issue. A framework can help to: structure discussions in systematic way by clearly defining the key elements or features of the problem; standardize terminology to make sure participants are talking about the same thing; and clarify assumptions, open questions, and areas of agreement or disagreement. The process of developing a qualitative framework provides a mechanism to incorporate technical experts in the assessment, and can engage experts from various fields and from different sectors. With varying levels of time and effort, a shared qualitative framework for potential implications of advances in S&T can be applied to assess a single research paper or proposal, a line of experimentation (e.g., studies of enhancing transmissibility of a virus), a research field (e.g., gain of function research), or to compare different capabilities to provide an assessment of relative potential risks among them.

Although there are numerous approaches and methods for assessing the potential risks of advances in S&T, there is nothing comparable for assessing potential benefits relevant to the implementation of the Convention. The project explored how one might begin to develop a framework that could enable structured discussions of the positive implications of S&T advances, including how to balance these with the mitigation of potential risks.

Applying the Frameworks to Potential Risks Using Illustrative Examples

The IAP and the US National Academies convened a meeting in Geneva, Switzerland, on 1 August 2019 to pilot the use of two qualitative frameworks developed to assess security concerns. Two hypothetical case examples illustrating types of scientific advances under discussion at the BWC and in other forums

I See, for example, Royal Society and International Council for the Life Sciences: *New approaches to biological risk assessment* (2009). London: The Royal Society (https://royalsociety.org/topics-policy/publications/2009/biological-risk/) and Morgan, K. (2005). "Development of a Preliminary Framework for Informing the Risk Analysis and Risk Management of Nanoparticles." *Risk Analysis* 25 (6): 1621–35. https://doi.org/10.1111/j.1539-6924.2005.00681.

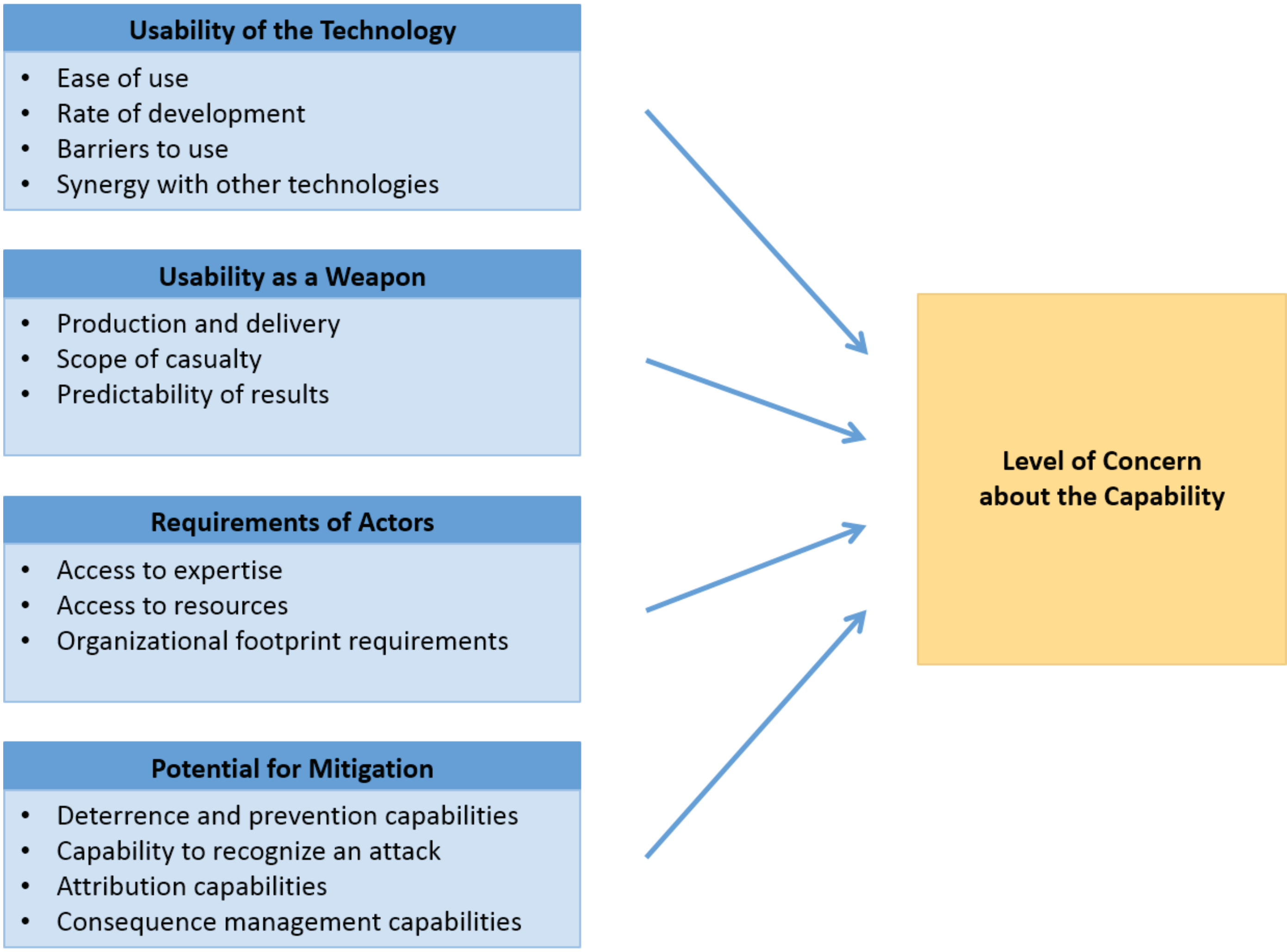


Figure 1: The US National Academies synbio framework.

were tested. The 30 participants had expertise in areas of the life sciences and chemistry, public health, and science and security policy, and came from 17 countries and 3 international organizations. This diversity of experiences enabled testing of the utility of the frameworks in facilitating communication across cultures, fields, and languages.

The first framework, developed by the US National Academies for the US Department of Defense to assess concerns posed by synthetic biology-enabled capabilities, consists of four primary factors: usability of the technology, usability as a weapon, requirements of actors, and potential for mitigation (see Figure 1)[II]. Each of these primary factors includes sub-elements that contribute to the analysis, while a report appendix provides illustrative questions to stimulate thinking about the relevant considerations. In applying this framework, one would generally proceed through a comparative factor-by-factor analysis, finally integrating the information across all four factors into a holistic assessment of the concern posed by a particular capability. This framework allows a user to analyze a capability in terms of the criteria that experts agree contribute to the level of concern about the capability.

This framework identifies a rich description of the set of key criteria applicable to analyzing a capability and to assessing the relative concern among a set of capabilities. It is intended to enable users to contribute their own technical or security expertise, to illuminate places where scientific or technical barriers exist as potential targets for monitoring progress, and to identify where further information is needed to clarify or revisit assessments. It provides a method for understanding risk, but does not explicitly identify policy options to address identified concerns.

The second framework was developed through the work of US chemical and biological nonproliferation researcher Jonathan Tucker to aid in identifying governance options to address

II National Academies of Sciences, Engineering, and Medicine. 2018. *Biodefense in the Age of Synthetic Biology*. https://doi.org/10.17226/24890. Reproduced with permission from the National Academy of Sciences, Courtesy of the National Academies Press, Washington, D.C.

biosecurity concerns posed by dual use technologies (See Figure 2)[III].

Tucker, Jonathan B., ed. Foreword by Richard Danzig., *Innovation, Dual Use, and Security*,

Use of this framework entails a multi-stage process,

Fig. 4.1 on p. 69, (c) 2012 Massachusetts Institute of Technology, by permission of The MIT Press.

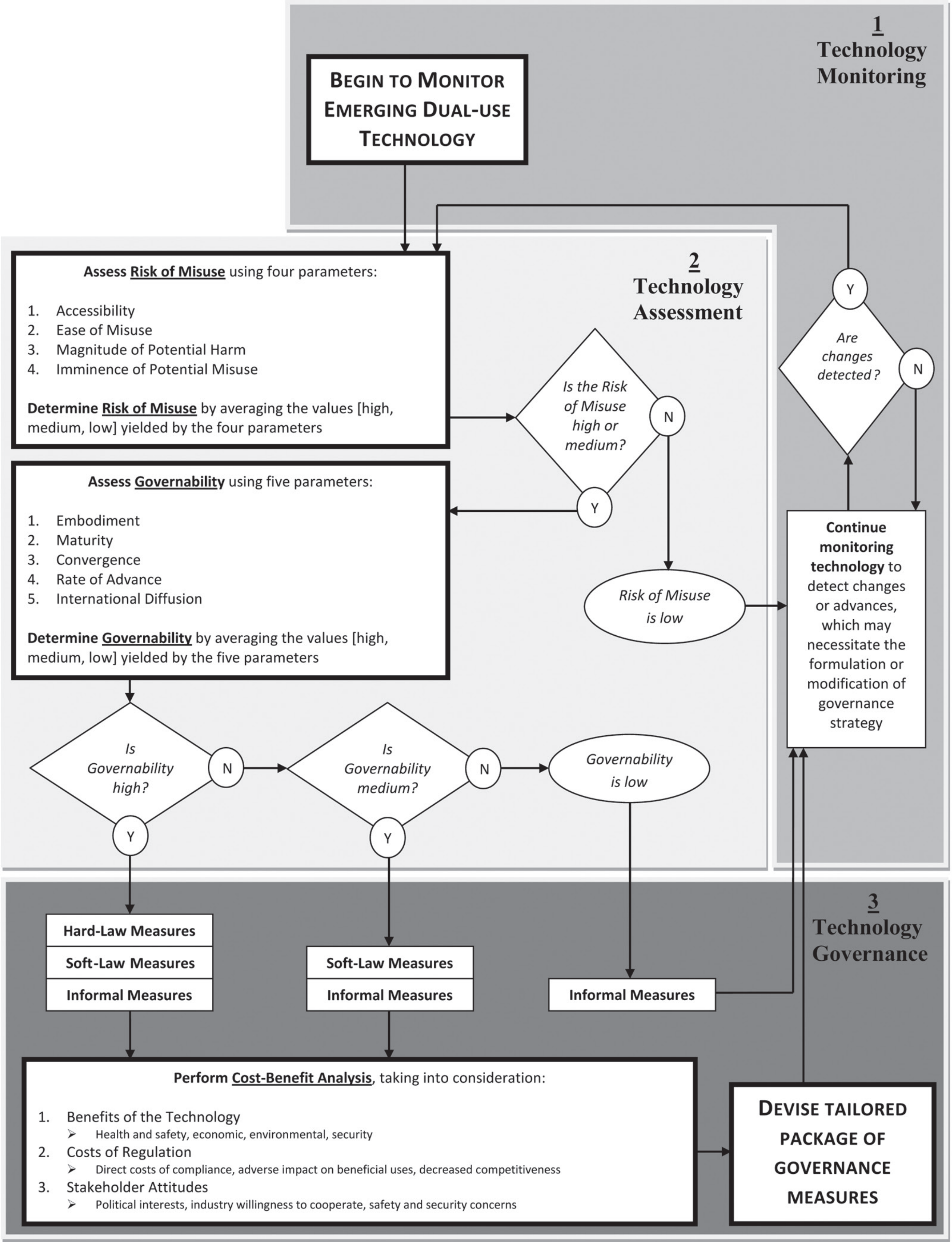


Figure 2. The Tucker framework.

starting with a technology assessment that addresses both the risk of misuse of a technology and its potential for governability.

Undertaking the first part of the assessment is similar to the 2018 National Academies' framework, asking the user to consider factors such as ease of misuse and magnitude of potential harm. In contrast to the National Academies' framework, the technology assessment is followed by the selection of applicable governance approaches and by a cost-benefit analysis to determine the most appropriate response strategy. Response strategies may entail continued monitoring of technical progress or undertaking other measures. In this way, the Tucker framework provides a decision tree that explicitly incorporates policy options in response to a technical evaluation. For the purposes of comparison across the two frameworks, the workshop focused on the technology assessment component of the Tucker technology assessment, which addresses the risk of misuse and governability. Participants at the meeting worked in groups of about 12-15 people to apply both frameworks to two illustrative case examples (see Box 1).

A discussion among all participants then explored how the use of each framework facilitated a structured conversation and what lessons were learned from the experiences.

Developing a Comparable Framework to Assess Potential Benefits

The final plenary session of the meeting focused on how to develop a comparable framework to assess potential benefits of advances in S&T. Participants shared suggestions for types of elements that might be part of such a qualitative benefits assessment framework.

Discussions under the BWC consider how to take advantage of new capabilities to support implementation of the Convention, and minimize or manage potential misuses of advances while not unduly impeding peaceful and beneficial applications. For example, S&T can contribute to the Convention under Articles VI and VII on investigating and responding to the alleged use of bioweapons, and in the encouragement of peaceful uses through Article X.

As a result, to be useful to the BWC a qualitative framework would ideally provide an ability to evaluate both risks and benefits, and a process for exploring how to achieve an appropriate balance to address them.

BOX 1
Hypothetical Case Examples
Used at the Meeting

These two case examples drew on illustrative scientific and technical advances as an opportunity for participants to work through the two frameworks; they were not intended to be comprehensive or fully realistic.

Case example 1: Change in transmissibility of an emerging viral pathogen

In this example, research to develop a vaccine for an emerging animal pathogen resulted in the generation of a human-transmissible strain. The example drew on capabilities such as access to databases of genetic sequences, the ability to make targeted mutations in viral genomes, and the generation of resultant live virus. It described a situation in which at least some experimental information was made available in the scientific community prior to discovery of the unanticipated and undesired result.

Case example 2: Engineering the microbiome

In this example, a common gut microorganism was engineered as a live microbial therapeutic to combat Clostridium difficile infection (a serious cause of hospital-acquired illness). The microorganism was engineered to produce a toxin whose expression would be switched on when a surface protein bound to C. difficile. A "kill switch" would also be inserted so that the engineered therapeutic strain could survive only in the presence of supplementing artificial molecules. This example drew on a number of synthetic biology techniques, as well as reflecting growing interest in the human microbiome as a therapeutic target.

Results of the Meeting

Both of the frameworks discussed at the meeting, and qualitative frameworks more generally, can be used for multiple purposes. One potential use is for science and technology assessments in the context of the BWC. The meeting began the process of identifying those features that worked well and those elements that may need to be further adapted to meet the needs of the Convention. In addition to use in global forums such as the BWC, they could be used by individual national agencies, as part of national or regional assessments, as tools for education and awareness raising of scientists about potential implications of their research, or for other purposes.

Both frameworks discussed at the meeting were useful in structuring the case study information to enable fruitful conversations. Interestingly, breakout groups using either framework reached similar conclusions about the implications and potential biosecurity concerns posed by the two hypothetical examples. For example, both frameworks led to greater concern with the case example on altering the properties of a viral pathogen, and less near-term concern raised by microbiome engineering capabilities. The Tucker framework enabled a relatively quicker screening of the risk of misuse, before proceeding to consider governability, while the National Academies' framework assessed the technical aspects in greater detail. But both frameworks were able to produce robust results.

Use of a framework approach to structuring information also revealed the value of using a group process to analyze the examples. Meeting participants spoke a range of languages and had varied areas of expertise. During the small group discussions, circumstances arose in which members interpreted components of the frameworks differently or envisioned differing circumstances that affected how they assessed a particular factor (for example, security risks that might be posed by users in a large, well-resourced laboratory versus by a small-scale actor operating in a lower-resource setting). Using a framework to guide the discussions as well as the face-to-face process helped to illuminate these differences quickly so they could be clarified or resolved. These characteristics may be particularly helpful in international settings and where there is a need to engage experts from very different fields or communities, as is common in BWC discussions.

When adapting or developing a framework for a new purpose, it is important at the outset for the key stakeholders to reflect and agree on how it can be tailored to best meet their requirements – e.g., by identifying, incorporating, and adjusting the terminology and assessment elements to be most applicable in the context of the particular use and to ensure clarity and common understanding. This process ensures that the framework includes the most relevant features and that there is buy-in from the community that will be using it.

Identifying the primary users of a framework would be a key component of adapting it to the needs of the BWC. Would these be technical experts from government agencies of different States Parties; would users include non-governmental academic and industry professionals; could they include States Parties' policymakers? Having up-to-date knowledge of the state of scientific capabilities and current limitations and bottlenecks contributes significantly to the technical assessment component of both frameworks. Would technical assessment be the primary purpose to which a BWC-relevant framework could be applied? On the other hand, subsequent steps in the Tucker framework result in governance and policy options. Are these useful in moving beyond "just the science" or might they be perceived as stepping into the area of authority of States Parties if used primarily by non-governmental technical experts?

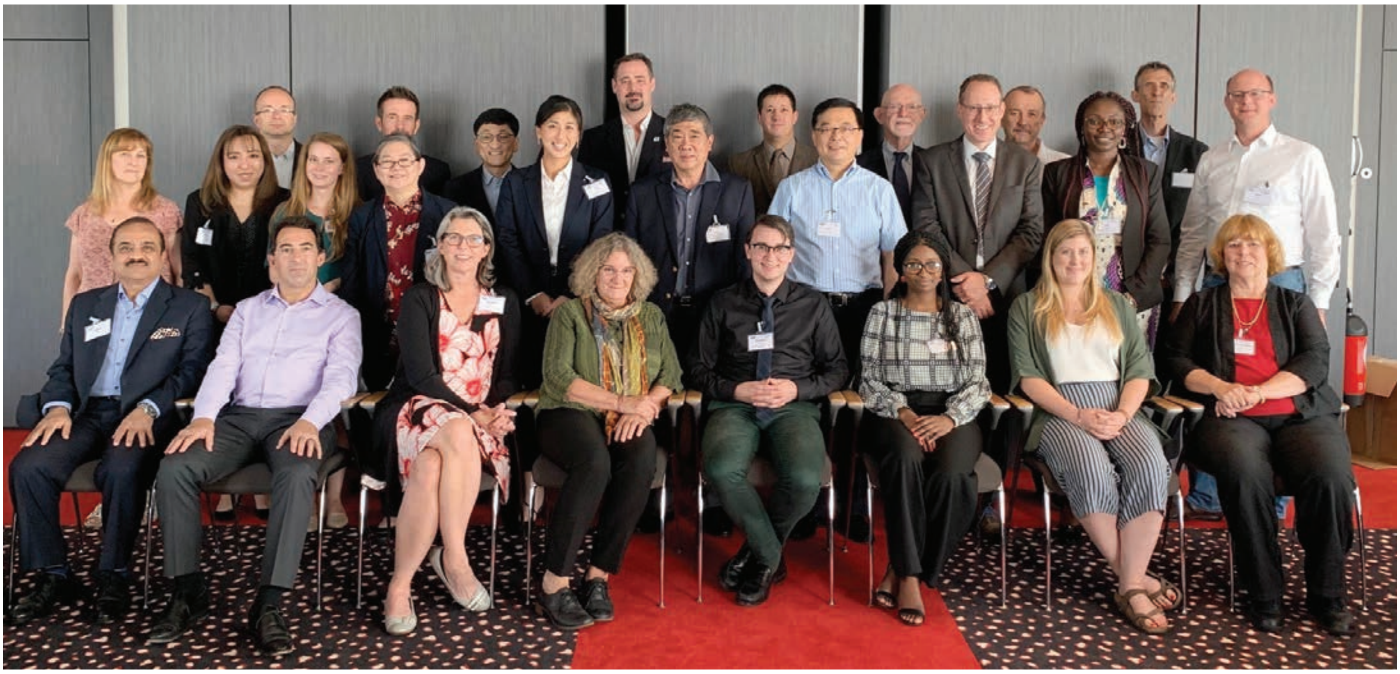
Several additional framework features would also be of value in any qualitative framework to be used in the context of the BWC. An important component of a BWC-relevant analysis will be identifying which types of developments or which circumstances are of more immediate concern for further potential action, versus which ones to monitor and revisit later. A generally accepted qualitative framework can also provide a structure for presenting information on S&T developments, risks, and benefits, facilitating comparisons across analyses undertaken by different States Parties or by external experts. Because one strength of a shared framework is that it sets out the core set of factors and considerations to be used, it also can serve as a critical first step in the development of more elaborate risk assessment and management approaches.

In the discussion, the participants began the process of considering a structured approach to analyzing benefits of scientific and technological advances, but more discussion is needed on this topic. Participants had different views on how similar the factors should be in the assessment of risks and benefits, for example. Some expressed an interest in using the same factors in both frameworks. For example, "Ease of Use" might be assessed as increasing concern but also as increasing the ability to capture a benefit. Others thought that the benefits factors should reflect broad categories for ways to consider how S&T can be used to help States Parties (in advancing public health, in aiding agriculture, in contributing to the bioeconomy, in improving biosafety and biosecurity practice, etc.). These questions were not resolved and further effort will be needed to find common ground on how assessment factors should be defined for a benefits framework and how to use the analyses to support optimizing benefits and mitigating risks. Another dimension requiring further discussion is how to capture the inherent uncertainty in the results of scientific research and in the timeline for realizing anticipated benefits.

Key Messages and Looking Ahead

Evaluating the utility of these two qualitative frameworks in the context of BWC-relevant S&T examples illuminated several key messages. Participants – from a variety of countries and backgrounds – successfully applied the frameworks, suggesting they are widely useful. Also, the process of using the frameworks to discuss S&T capabilities organizes information in ways that clarify areas of agreement, bring forward questions, and facilitate productive discussions. In this way, the frameworks enable security risks to be assessed in a systematic way to inform policy makers and support the goal of evidence-informed policy. A parallel framework or section of a framework to promote understanding and assessment of the benefits of technologies could also be developed, a process only begun during the meeting.

Looking ahead, the development of a framework to address potential risks that meets BWC needs will require further opportunities to adapt and test ideas. It would also be useful to conduct preliminary research to propose a related benefits framework. The work for both risks and benefits should include additional groups of intended users and use different types of case examples in order to capture the breadth of issues that have implications for the Convention. This process could continue testing how framework elements can be adapted and which new framework elements for benefits can be identified to support the Convention. Discussion and input from States Parties will also be needed to clarify the ways in which a BWC-relevant framework might be used in the context of the Convention and who the primary user communities could be. Continuing to use and adapt qualitative frameworks for S&T assessment purposes other than application to the BWC will also continue to provide valuable insights.



On 1 August 2019, the InterAcademy Partnership (IAP) and the US National Academies of Science, Medicine and Engineering (US NASEM) hosted a workshop on ‘Frameworks for Assessing the Risks and Benefits of Advances in Science and Technology: An experts meeting to inform the States Parties of the Biological and Toxin Weapons Convention’ during the Meeting of Experts of the Biological and Toxin Weapons Convention (BWC) in Geneva, Switzerland.

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