Biological and Toxin Weapons Convention
Meeting of Experts,
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Developments in Science and Technology

Submitted by the United States of America

Background

The Seventh Review Conference established a standing agenda item on "review of developments in the field of science and technology." While the agenda item consists of a number of sub-items, it has two major elements. The first is a review of S&T developments potentially relevant to the BTWC, with a different area of emphasis each year. The second addresses how such developments should be managed -- questions of national oversight, scientific responsibility, outreach, and education. This bifurcated approach is important: the definition of biological weapons contained in Article I is sufficiently broad and flexible that relatively few S&T advances are likely to raise questions about the scope of the Convention. More often, the key question for States Parties to consider will be whether these developments have implications for how we implement the Convention—that is, questions of governance. Discussion under this agenda item should increase shared understanding of the implications of the ongoing revolution in the life sciences—an understanding not only of the risks posed by this technology, but also the benefits. Only by understanding both risks and benefits can States Parties make informed choices about how to manage risks.

Advances in Enabling Technologies

States Parties agreed to focus in 2012 on "enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology." Such technologies have enabled, and continue to contribute to, significant advances in the life sciences such as greater understanding of infectious disease biology at cellular and molecular levels, development of new vaccines and treatments for emerging infectious diseases, and increased diagnostic accuracy and speed for disease surveillance. However, these technologies could potentially be used for purposes contrary to the Convention, including the making pathogens or toxins easier and less expensive to manufacture *de novo*, and further into the future, enabling development of biological weapons agents designed to evade countermeasures or target certain human populations.

The full future impact of these technologies is difficult to assess. What is clear, however, is that there are a number of "enabling" technologies and developments that underpin many of the advances and discoveries in the life sciences. Advances in these enabling areas will allow research and applications of the life sciences to proceed at a faster pace; conversely, limitations in these areas can constrain progress. This has a number of implications: first, the rate of change in enabling technologies is a leading indicator of the pace of broader advances in the life sciences; second, because many of these technologies are interdependent, a "bottleneck" in a single area can limit the rate of advances across a broad range of scientific efforts; and third, regulatory and oversight efforts, where required, must be undertaken in a way that is sensitive to these effects. Although a more exhaustive review is provided in the background paper provided by the ISU (BWC/MSP/2012/MX/INF.1), examples of fundamental enabling technologies include:

Gene Sequencing: The speed of sequencing technologies has continued to increase rapidly, while the cost per base pair has dropped dramatically. Therefore, far more genetic data can be sequenced and analyzed, allowing researchers to extract more information from their research. As more sequences become known, and as relationships between genetic sequence and gene function are elucidated, our understanding of how organisms function at a very basic level expands – understanding that can be applied in a wide range of ways.

Gene Synthesis: DNA (or RNA) synthesis is now widely available commercially. Like sequencing, costs continue to drop and speed and capability continue to increase. The ability to synthesize genetic material – much more rapidly and efficiently than could be effected using older recombinant techniques – has important implications for both advancing our understanding of biology and for application of that understanding. Synthesis technologies can be used to modify genes in order to study their function, and are key to certain types of research, particularly "gain-of-function" experiments. DNA synthesis can also be used to apply that increased understanding, for example by modifying yeast or algae to produce a desired molecule. Such "bioprocessing" is increasingly used in industry as a production technology.

Processing power: Some life science work (e.g., systems biology modeling, modeling protein folding) depends heavily on computational power. Living systems are complex, and even efforts to develop reductive models often involve modeling a large number of interacting variables. Despite the growth in computer processing power illustrated by the famous "Moore's Law," raw computing power can still have a rate-limiting effect in some areas. This limitation has been partially offset through creative use of "distributed computing." One of the best-known examples of this has been the "Folding@Home" project initiated by Stanford University in 2000, a distributed computing simulation used to better understand protein folding – a topic of great academic interest, and also significant potential application in improving our understanding of a number of diseases. Thousands of individuals around the world volunteer idle processing time on their PCs (and even PlayStation3 game systems), which then run calculations for Folding@Home simulations.

Data Storage and Network Bandwidth: The volume of genomic, proteomic, and other data generated by researchers continues to grow. This information is often useful not only to the individual research team, but through its contribution to our broader understanding of these fields, and the aggregation and analysis of such data has given rise to an entire field known as bioinformatics. Databases such as GenBank thus become increasingly important tools for the research community. The sharp decrease in data storage costs over the past decade, and the increased availability of broadband internet connections, have thus played an important enabling role for the life sciences.

Implications

These few examples of enabling technologies were selected to illustrate a few important points:

- To have a broad enabling effect, a technology must be widely used, and this in turn means that it must not only be available, but sufficiently rapid and affordable to be employed. As speed and reliability increase, and cost decreases, the potential impact on the life sciences will tend to grow.

- Technologies are interdependent. Part of the impact of gene sequencing technology stems from the increasing availability of genomic, proteomic, and other data that can be used by other researchers, as well as from the ability to apply this information using gene synthesis. Thus sequencing, synthesis, processing power, data storage, and network bandwidth have important synergistic effects.

- Key enabling technologies are not limited to the life sciences.

- Many enabling technologies require States Parties' awareness and understanding, rather than any specific action. Of the technologies described above, the only one the United States has identified as requiring action from a biosecurity standpoint is DNA synthesis: in 2010, the Department of Health and Human Services issued the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*[1] to assist commercial providers in screening customers and orders to guard against potential misuse. The U.S. Government is currently in the process of assessing the extent to which industry has implemented this guidance and its impact.

Strengthening National Biological Risk Management in Research and Development; Codes of Conduct; Outreach and Education

The United States supports an integrated risk management approach that encourages peaceful uses of life sciences and, at the same time, guards against their misuse. This includes export control measures as well as appropriate biosafety and pathogen security measures (which are also addressed under the Standing Agenda Item on National Implementation), but it also includes efforts to address the dual-use risks posed by life sciences research. While technologies throughout history have been "dual-use," the risks posed by technologies are not uniform, and some require greater efforts at risk management. Increased understanding of, and ability to manipulate, living systems at basic levels promises tremendous benefits to human health and economic development. Misused, however, the same understanding and ability hold significant potential for harm.

Managing such dual-use risks requires efforts to identify, and where appropriate, mitigate risks throughout the life cycle of research. If risks are not identified until the research has been completed and manuscripts submitted for publication, for example, very few options may be available to manage those risks, and the options that are available may be drastic or inadequate.

In recognition of this, the United States Government issued in March 2012 a policy governing all federal agencies funding and/or conducting life sciences research.[2] This policy requires agencies to evaluate certain types of research to determine whether they constitute "Dual Use Research of Concern" (DURC) and to implement mitigation measures, as necessary, to lower potential risks. The DURC designation means that the research can be reasonably anticipated to produce results that could be directly misused for harmful purposes with significant effect. Identifying research as "DURC" does not mean, necessarily, that the research should not go forward; rather, it means

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[1] http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf

[2] http://oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf

that the funding agency should work with the researchers to clearly identify the risks and develop an effective plan for mitigating them.

The United States is also in the process of developing a complementary policy that would require institutions receiving federal research funds to put in place their own DURC oversight mechanisms. Purely national efforts, however, are of limited utility, since life science research is a global enterprise. We call on all BTWC States Parties to consider how best to manage the risks of dual-use research of concern.

For such oversight to be effective, however, more is needed than clear policies and regulations. The understanding and support of the scientific community are critical, as they will not only be affected by these policies and regulations, but responsible for implementing them. Efforts are needed to engage with the scientific community, to increase their awareness of dual-use research risks and mitigation measures, and to work with them to strengthen and reinforce the culture of responsible science. Moreover, effective engagement will provide policymakers a better understanding of the research landscape and assist in risk/benefit assessment. In this context, we welcome the discussions held by the American Society of Microbiology, the Royal Societies of the Netherlands and the United Kingdom, and the U.S. National Academy of Sciences on the implications of the recent H5N1 research controversy. We encourage these groups to share their views on how governments can best support responsible conduct.

The United States supports responsible conduct of life science research, including the development of standards and tools for laboratories and other practicing institutions. Within the life sciences community, these standards and tools can establish norms as well as promote positive communication with the public. Life science practitioners should be actively engaged in these developments to ensure that they are accepted, effective, and do not unduly hamper peaceful uses of the life sciences. Furthermore, the United States supports education and outreach as mechanisms to raise awareness about safety, security, and dual-use issues among life science practitioners and to prevent exploitation of S&T for malicious purposes. For example, the U.S. government established a website called "S3: Science, Safety, and Security" (www.phe.gov/s3) to encourage transparency and promote broader awareness about the evolving nature of biological agents that can be hazardous, and how to handle and use these agents safely and securely. Education and outreach are perhaps the best tools States Parties can use to sensitize life science practitioners to security issues, as well as to their perceived role as holders of public trust.

Recommendations

The 2012 Meeting of States Parties should:

1. Acknowledge that advances in "enabling technologies" affect not only the pace of scientific developments, but also how science is conducted and applied; over time, such advances may therefore have implications for how States Parties implement the Convention;

2. Note that DNA synthesis technology, while overwhelmingly beneficial, has potential for misuse;

3. Urge relevant States Parties to consider options for minimizing this potential, such as sequence and order screening, while simultaneously minimizing any negative impacts on the conduct of research and business operations;

4. Recognize that the dual-use nature of some life sciences research requires thoughtful approaches to maximize benefits and minimize risks of accident or misuse;

5. Call upon States Parties to examine, at a national level, means of appropriately managing the risks of dual use research of concern throughout the research lifecycle;

6. Invite the scientific community, academia, and industry to share their views on how governments and the BTWC can better support them in education, outreach, and other efforts to reinforce the culture of responsible science;

7. Invite States Parties, on the basis of stakeholder input, to provide such support where feasible.