BWC/WG/2/WP.4

# Working Group on the Strengthening of 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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Agenda item 6
**Identifying, examining and developing specific and effective measures, including possible legally-binding measures, and making recommendations to strengthen and institutionalize the Convention in all its aspects within the mandate of the Working Group**

## Advances in Science and Technology: Background for Discussion of Measures to Strengthen the Biological and Toxin Weapons Convention (BWC)

### Submitted by the United States of America

*Summary*

This paper outlines scientific and technological (S&T) advances since the 1990s to inform measures States Parties can take to strengthen the Convention. S&T advances have demonstrated remarkable benefits. Advances in biotechnology are becoming more democratized and broadening the scope of research, development, and manufacturing around the world. However, some of these advances can also expand the ways in which weapons could be developed or produced, with reduced detectability. It is beneficial for States Parties to have structured and regular advice on S&T issues to keep apprised of such developments of relevance to the Convention as biotechnology continues to evolve.

# I. Unprecedented changes in biological science and technology over the past 30 years

1. Revolutionary scientific and technological developments over the past three decades, have made manipulating biological systems faster, cheaper, easier, and more accessible. An entire biotechnology industry has rapidly developed, with numerous, growing applications and innumerable users worldwide. The background paper[1] the Implementation Support Unit prepared for the 9th Review Conference elaborates on the many ways that rapid advancements in science and technology over the last ten years can relate to the BWC. These include major advances in nucleic acid and peptide synthesis, genetic sequencing and engineering, analytics and information processing technologies, vaccines and therapeutics, disease surveillance and diagnostics, big data, machine learning, artificial intelligence, and more.

2. This paper outlines a few illustrative examples of important advances in the tools and directions of biological sciences related research, development, and industrial activity.

## A. Revolution in research tools

3. Significant advances in research tools have enabled scientists to understand and manipulate biology more quickly and with greater precision than previously possible. Advancements in genome sequencing along with other biomolecular analytical tools greatly increased the sheer amount of information we have about biological organisms and the functions of their component systems. A series of advances in genetic engineering have transformed what can be edited, how quickly and precisely it can be edited, and—with increased availability—who can edit genes. Machine learning and information processing advancements reshaped how researchers do experiments: a lot more can be modeled or predicted in a computer before any laboratory work begins.

4. Illustrative examples of how research tools have transformed since the 1990s include:

- The Human Genome Project launched in 1990 to sequence the genetic material in a human cell took over 13 years to complete and cost around $3,000,000,000. In 2021, researchers sequenced a human genome in around 5 hours and for under $1,000[2];
- The application of CRISPR gene editing technology dropped the time needed to generate mouse models to mimic disease pathology in humans from years to weeks[3];
- In 1994, the "CASP" competition was launched to try to predict protein structures (which govern protein activity) and made slow progress over the next 25 years. In 2021, the artificial intelligence company DeepMind predicted 1 million three-dimensional protein structures using the machine-learning program called AlphaFold. One year later in 2022, they unveiled an additional 199 million predicted three-dimensional protein structures[4].

## B. Biomedical research today does not just respond to outbreaks, it prepares for them

5. The world experienced a series of devastating outbreaks over the past 30 years – Ebola, Zika, HIV/AIDS, SARS, MERS, COVID-19, and swine and avian influenza among

[1] https://undocs.org/en/BWC/CONF.IX/7.

[2] https://css.ethz.ch/content/dam/ethz/special-interest/gess/cis/center-for-securities-studies/pdfs/CSSAnalyse321-EN.pdf .

[3] https://www.genengnews.com/topics/genome-editing/three-ways-crispr-is-making-animal-research-models-more-predictive/.

[4] Jumper, J., Evans, R., Pritzel, A. *et al.* "Highly accurate protein structure prediction with AlphaFold." *Nature*, vol. **596**, 2021, pp. 583–589. https://doi.org/10.1038/s41586-021-03819-2.

others. Since it is a question of when (not if) the next outbreak will occur, epidemiologists and infectious disease scientists increasingly work to surveil, predict, and prepare for outbreaks. This anticipatory research direction comes with more activities focused on disease surveillance, diagnostic and laboratory capabilities, and development of vaccines and other countermeasures than ever before.

6. Illustrative examples of how outbreak preparedness has changed research include:

- During the COVID-19 pandemic, as SARS-CoV-2 variants were detected, they were quickly reproduced and characterized, including to inform whether existing medical countermeasures were effective. Increasingly, genomic sequencing plays a key role not only in disease surveillance, but in guiding outbreak response;
- Within the past decade, there have been more instances of experimentation to identify pathogen mutations that would enhance their transmissibility or other factors in order to inform surveillance efforts;
- To shorten the timeline to research, develop, and synthesize effective medical countermeasures for future outbreaks, a new approach is increasingly being pursued – work on representative, or “prototype,” pathogens from key viral families. The response to the COVID-19 pandemic, which built on extensive prior work on SARS and MERS, has demonstrated that such an approach offers significant benefits for preparedness[5].

## C. Biotechnology in the 21st Century is an industry with innumerable applications

7. Much like the invention of computers and the internet, biotechnology applications are broader today compared to the originally niche field that developed tools for biological scientists. Today, biotechnology is used by brewers and wineries, by pharmaceutical companies to produce medicines more efficiently, by crop producers to safeguard crop yields, by scientists seeking to develop biofuels or accelerate plastic degradation, and even by "do-it-yourself" experimenters around the world innovating beyond established laboratories. Scientific breakthroughs in the fields of metabolic engineering, production, manufacturing, and distribution systems expanded the potential uses—and users—of biotechnology well beyond medicine, to include bio-based polymers, specialty chemicals, biofuels, and other products.

8. Illustrative examples of biotechnology and biomanufacturing being used for myriad purposes include:

- In 1999, the first companies to synthesize genes commercially were formed. Now, the cost of synthesis is as low as 7 cents (USD) per nucleotide[6] (the basic building block of DNA) and, in 2022, the global market was valued at 1.76 billion USD[7];
- After almost 20 years of dedicated effort, a vaccine against Haemophilus influenza type b was licensed in 1985.[8] In contrast, in 2020, multiple safe, effective, and high-quality vaccines against the novel SARS-CoV-2 virus were researched, developed, and manufactured at scale in just one year from when the outbreak was reported;

[5] M Cristina Cassetti and others, Prototype Pathogen Approach for Vaccine and Monoclonal Antibody Development: A Critical Component of the NIAID Plan for Pandemic Preparedness, *The Journal of Infectious Diseases*, Volume 227, Issue 12, 15 June 2023, Pages 1433–1441, https://doi.org/10.1093/infdis/jiac296

[6] https://www.twistbioscience.com/products/genes.

[7] https://www.grandviewresearch.com/industry-analysis/gene-synthesis-market-report.

[8] A Brief History of Vaccination (who.int).

- In recent years, proof-of-concept experiments introduced the potential for DNA to be used as an information storage device akin to flash drives[9];
- Today, agriculture producers frequently use biotechnology to improve nutrition, sustainability, and other qualities of crops and production. For example, the "arctic apple" is widely commercialized today and uses a biotechnology that was first developed in the 1990s (transgenic RNA interference) to delay browning.[10] There are similar examples for potatoes,[11] rice,[12] and even microbial fertilizers[13];
- Between 2000 and 2020, nearly 700 new prescription medications were approved by the U.S. Food and Drug Administration alone – an increasing proportion of which are biological products[14].

## D. Biotechnology has become a major component of national economic development

9. In the last thirty years, and particularly in the last decade, advances in the biological sciences have led to rapid economic growth in the biotechnology sector of many countries. Companies around the world have been established to apply those advances to practical, product-driven applications.

10. Some indicators of this include:

- The term "bioeconomy" was new in the 1990s. Today, some estimates anticipate that the bioeconomy will grow to over $30 trillion USD globally in the next two decades;
- Growth in investments in synthetic biology companies. In the last five years, annual global funding for synthetic biology increased from nearly $2 billion in 2017 to more than $10 billion in 2022;
- Growth in the number of synthetic biology companies. Globally, the number of synthetic biology companies founded each year has grown almost three-fold, with only 370 companies established 10 years ago and more than 1030 companies established in 2022;
- Compared to 1996-2002, the number of patents granted for biotechnology by the U.S. Patent and Trademark Office increased by nearly 300% in 2002-2015[15];
- In 1993, the Nasdaq Biotechnology Index was launched and, just between 2010 and 2021, the number of its components nearly tripled[16];
- Adoption of national policies to promote biotechnology. Many countries have recognized the enormous potential of biotechnology in many different fields and more than 50 nations have put in place related national goals and strategies. As just one example, the Ministry of Science and Technology of Thailand adopted a National Biotechnology Policy Framework for 2012-2021, which prioritized four strategic sectors (health, energy, industry, and agriculture) that could excel through the application of biotechnology.

11. All indications point to a rapid increase in the biotechnology sector of national economies that is expected to continue for the foreseeable future.

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9 https://www.harvardmagazine.com/2021/03/right-now-dna-storage.

10 https://www.smithsonianmag.com/smart-news/first-non-browning-gmo-apples-will-go-sale-next-month-180961875/

11 USDA approves next-generation GM potato | Nature Biotechnology

12 Golden Rice is safe to eat, says FDA | Nature Biotechnology

13 Microbial Fertilizer as an Alternative to Chemical Fertilizer in Modern Agriculture | SpringerLink

14 https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Innovation_in_Biopharmaceuticals.pdf

15 https://www.uspto.gov/web/offices/ac/ido/oeip/taf/data/biotech.htm

16 https://www.nasdaq.com/articles/the-biotech-trek%3A-a-short-history-from-1993-to-2021-2021-06-29

# II. Scientific and technological advances impact both sides of the equation of peaceful vs. prohibited activity – A possible role for scientific advice?

12. The advances described here are merely a few examples of significant changes in the biological sciences and biotechnologies, and they can bring substantial and growing benefits for humankind. Further, these tools are more widely accessible than ever before and the peaceful cooperation among scientists, platforms for open sharing of data, and rapid, open publication of research continue to grow. This sharing of scientific information, including research and development results, is led by academia, industry, and governments; for example, the Biden-Harris Administration named 2023 the Year of Open Science and, as a member of World Wide Science[17], made dedicated efforts to share even more.[18]

13. In addition to their economic and public health benefits, advances in biotechnology can also provide useful tools for international efforts to detect and combat outbreaks, including possible biological weapons-related ones. As one example, wastewater surveillance—first used for polio detection, but most recently applied with today's genomic surveillance technology to monitor for SARS-CoV-2 variants—could be applied as a sentinel system for other pathogens.[19] Advances like this and others can help early warning, medical counter measures, and identifying the source of outbreaks, regardless of their cause.

14. While this progress is worth celebrating, the same progress and spread of capabilities could be misapplied for the development of biological weapons. While the ways such biotechnological advances could be misused are wide-ranging, one notable change from what was considered 30 years ago is that such advances have made it easier to support a biological weapons program at a smaller scale of development, but potentially have a disproportionately greater impact. For example, advances in protein engineering have the potential to make toxin production for weapons purposes cheaper, simpler, and harder to detect than in historical BW programs. With today's technology, a nefarious actor acting in a manner inconsistent with the Convention could do so without the characteristics that used to be associated with historical government-run large scale biological weapons research and production efforts. Whether it is a non-State actor or State biological weapons program, detecting clandestine activity is more challenging today, since there is less need for a large team of highly specialized scientists, a large laboratory or testing facility, or a high level of production equipment.

15. As the rapid acceleration of scientific and technological advancements impacts the potential for both peaceful and prohibited activities, the BWC needs to keep pace. More structured scientific and technological advice, input, and discussion could help ensure BWC States Parties are regularly informed of scientific and technological developments and the impact they have on the Convention and its implementation.

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[17] https://worldwidescience.org/

[18] https://open.science.gov

[19] https://www.nature.com/articles/s41591-022-01940-x