Emerging Biotechnologies and the 1972 Biological Weapons Convention: Can it Keep Up with the Biotechnology Revolution?

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TABLE OF CONTENTS

I. INTRODUCTION TO THE BIOTECHNOLOGY REVOLUTION AND REGULATION—THE ISSUE .......................... 695

II. WHAT PROCESSES IN THE BIOLOGICAL WEAPONS CONVENTION ENSURE KEEPING UP WITH SCIENCE? .... 697
   A. First Review Conference (1980) ............................... 698
   B. Second Review Conference (1986) ............................ 703
   C. Third Review Conference (1992) .............................. 707
   D. Fourth Review Conference (1996) ............................ 707
   E. Fifth Review Conference (2002) ............................... 707
   F. Sixth Review Conference (2006) .............................. 708
   G. Seventh Review Conference (2011) ........................... 710

III. THE SCOPE OF THE ARTICLE I DEFINITION ..................... 712

IV. COULD THESE ALSO BE CONSIDERED WITHIN THE SCOPE OF THE BWC? ............................................. 715
   A. Invasive Species .............................................. 715
   B. Nanobiotechnologies ......................................... 716
   C. Biotechnology Weapons (Physiological and Psychological Substances) ........................................ 716

V. CONCLUSION ......................................................... 718

I. INTRODUCTION TO THE BIOTECHNOLOGY REVOLUTION AND REGULATION—THE ISSUE

The biotechnology revolution, sparked by the 1950s discovery of the DNA double-helix by James Watson and Francis Crick, has shown us what was unimaginable in the first half of the twentieth century.1 Manipulating this DNA to perform useful tasks and purposes to make our quality of life grew exponentially, and even accessibility to these discoveries has seen vast expansions. Synthetic biology in the 2000s brought another leap in accessibility to building biological machines,
and it no longer required graduate student training to manipulate DNA—now high schools students are doing this in their garages.\footnote{See e.g., John Schwartz, \textit{Fish Tale Has DNA Hook: Students Find Bad Labels}, \textit{N.Y. Times} (Aug. 21, 2008), http://www.nytimes.com/2008/08/22/science/22fish.html (reporting about high-school students exposing the sushi restaurant for passing tilapia as white tuna).}

To say that the law has kept up with these leaps in technology and its integration into today’s society would be right on one hand because law has no choice but to deal with the facts before it with the law at hand. But on the other hand, existing law has been re-interpreted to reach the scope of these technologies, often to a point of needing to draft new laws, like the Genetic Information Nondiscriminatory Act of 2008 (“GINA”), to protect privacy of individual genetic testing. But like GINA, which took ten years of being introduced and failing in Congress before it was passed, it is very slow going to develop new laws. Accessibility has also proven challenging in the context of intellectual property law. Subsistence farmers, who might have been starving on the productivity level of native crops, could enjoy increased sizes of harvests and feed their families, and even sell the surpluses like never before. The legal impediments once thought to make these intellectual properties inaccessible to the remote regions of the world have become more reasonable and inclusive, and will continue to be so, although this, too, has been slow in coming relative to the leaps in technology.

Like almost all emerging technologies, the first manipulations may not be useful but amount to little more than “parlor tricks,” such as building bacteria that smell like bananas or writing IBM’s name in nano-size with atoms that could only be seen with a microscope. These “parlor tricks” were soon to be parlayed into useful and powerful tools of the trade.

So it follows that the leaps in technology have also made it possible to use these discoveries to do great harm in the hands of the malevolent individual or nation with increasingly less talent, skill, and knowledge, as can be seen with the synthetic biology technology that is so accessible even to individuals with a weekend of training. Then how has the law kept pace with inventive doers of harm? Particularly, how has international law kept pace with the technologies that might evolve from the biotechnology revolution?

One of the areas arising from the biotechnology is the bionanotechnology explosion in discoveries that holds great promise for human health, but it is also largely unregulated. Many of these technologies are relegated to military research for national defense with little public scrutiny. The great explosion in synthetic biology in the 2000s has spawned the iGEM Competition, where students from around the world convene in the United States to compete in creative
biological craftiness.³ Craig Venter, the legendary progenitor of the race to map the human genome, sponsored the May 2014 report that warned: “Genetically engineered organisms are increasingly being developed in ways that leave them outside of APHIS’ authority to review, and synthetic biology will accelerate this trend.”⁴

In light of the quandaries presented by domestic law, has the Biological Weapons Convention of 1972⁵ (“BWC”) also been so outpaced by the technologies that it is no longer effective and meaningful in international law? Part II will examine the continuum of official actions that have attempted to keep pace with the growing biotechnologies that may present threats to global biosecurity through interpreting the BWC. Part III looks at how these definitions may not be sufficient. Finally, Part IV looks at other mechanisms that may provide a better way of controlling biological weapons than redefining the technologies through the current processes.

II. What Processes in the Biological Weapons Convention Ensure Keeping up with Science?

The Biological Weapons Convention, drafted and then signed in 1972, defines biological weapons as “[m]icrobial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.”⁶ The treaty in Article XII provides for the meeting of the parties five years after entry into force, or earlier upon parties’ request:

> to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.⁷

Thus, the parties understood they were standing in the middle of a biotechnology revolution and that there was a clear need to meet every five years to assess any new technologies that were relevant to the treaty.

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⁶. Id. art. I.
⁷. Id. art. XII.
TEXAS A&M LAW REVIEW [Vol. 2

A. First Review Conference (1980)

That progress in scientific and technological advances should be monitored was first recognized in the BWC itself in Article XII’s directive to “take into account any new scientific and technological developments.”8 Further, the Preparatory Committee for the First Conference asked for a special report to be compiled by the three Depository Parties (the United States, the United Kingdom, and the Soviet Union) to address those advances that was to be distributed about a month before the First Review Conference, which was held in March 1980. In the preparatory report, they decided to ask the Depository Governments to prepare a background paper on new scientific and technological developments relevant to the Convention and the Secretary of the Committee would invite the comments of States parties on the background paper. The Committee further decided to invite States parties who wished to do so to communicate to the Secretary of the Committee their views on new scientific and technological developments relevant to the Convention. The Committee further decided to request the Secretary of the Committee to compile the comments of States parties on the paper prepared by the Depository Governments together with national contributions and to provide these documents to States parties at the Review Conference.9

The comments of the parties reveal the perception of the advances in science at the time and the risk for the future. In the summary document on Article XII, the party from the United Kingdom, D.M. Summerhayes, reported that the report had “reached the conclusion that recent scientific and technological developments had not called into question the effectiveness of the Convention, would be given the detailed attention in deserved; in his view, a thorough examination of the paper could best be conducted in a working group.”10 The U.S. representative, Charles Flowerree, “as co-author of the background paper on new scientific and technological developments relevant to the Convention, shared the view of the United Kingdom and the Soviet Union that all these developments were already adequately cov-

8. Id.
EMERGING BIOTECHNOLOGIES AND 1972 BWC

2015

...ered by the provisions of the Convention.\footnote{11}{Id. ¶ 23.} The First Review Conference was still deciding the issue of whether there should be subsequent review conferences every five years, since the Convention called for only the first one.\footnote{12}{Id.} The representative for Bulgaria, Petar Voutov, made the observation that “there was quite an intensive exchange of scientific information in that field and that the exchange could reasonably be expected to increase even further.”\footnote{13}{First Review Conference 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, Mar. 3–21, 1980, \textit{Final Document of the Review Conference of the Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Fifth Meeting}, ¶ 12, U.N. Doc. BWC/CONF.I/SR.5 (Mar. 6, 1980), available at http://www.unog.ch/bwcdocuments/1980-03-1RC/BWC_CONF.I_SR.05.pdf.} Brazilian Ambassador Celso Antonio de Souza e Silva observed that “[a]dvances in biology, bacteriology, toxicology and chemistry were of direct relevance since, as was clear from the background paper submitted in document BWC/CONF.I/5, technology that could be used for hostile purposes was also needed for such important peaceful purposes as medicine, agriculture and industry.”\footnote{14}{First Review Conference 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, Seventh Meeting, ¶ 5, U.N. Doc. BWC/CONF.I/SR.7 (Mar. 7, 1980), available at http://www.unog.ch/bwcdocuments/1980-03-1RC/BWC_CONF.I_SR.07.pdf [hereinafter First Review Conference, Seventh Meeting].} This statement was perhaps the first reference to the dual-use problem that would come to dominate the discourse a decade later. The representative from Yugoslavia, Marko Vrhunec, noted:

Each State party was particularly responsible for the activities of persons or organizations which might acquire biological agents or their products within its territory for the purpose of inflicting harm on other States. It was a well-known fact that research in molecular biology, particularly in so-called “genetic engineering,” could involve accidental and unpredictable risks affecting not only the institution and the country in which the research was taking place but other countries as well.\footnote{15}{Id. ¶ 26.}

Genetic engineering was apparently considered a well-known technology at the time of the first meeting of the parties.\footnote{16}{Genetic Timeline, Nat’l Human Genome Res. Inst., https://www.genome.gov/Pages/Education/GeneticTimeline.pdf (last visited Oct. 14, 2015).} Based on the report, Mr. Grekov, the representative of the Byelorussian Soviet Socialist Republic, made the bold conclusion from the report that “[i]t was also evident that scientific and technological developments rele-
vant to the Convention were not creating new capabilities or incentives for the clandestine violation or circumvention of the Convention."17 The representative from Hungary, Mátyás Domokos, pointed out that the convention was adequate with regard to Article XII, asserting that position in connection with the conclusion in 1977 under the auspices of the World Intellectual Property Organization, of the Budapest Treaty, on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure.18 Alfonso Garcia-Robles of Mexico was more specific in his reference to the report, which he quoted, saying: “‘developments in the ability to manipulate genetic material intentionally should be followed closely and periodically re-evaluated’, and the other, in paragraph 17 of section II (New Infectious Diseases), which read ‘it may be useful in the future to evaluate the implications of eradication of smallpox and other infectious diseases.’”19 The eradication of smallpox from the world, announced by the World Health Organization in 1978,20 led to the signing of a treaty to monitor the depositories of smallpox and decide whether they should be destroyed or preserved.21 Soussan Raadiazarakhchi from Iran noted that “it was clear from the conclusions in the [report] BWC/CONF.I/5 that progress in scientific and technical fields concerning the Convention had had little impact on its effectiveness.”22

Turning to the report itself, the categories of science and technology in this context were identified as follows: (1) recombinant DNA techniques; (2) new infectious diseases; (3) chemical synthesis of toxins; (4) the industrial use of fermentation techniques; (5) microbial control of pests; and (6) scientific and technological findings.23

19. Id. ¶ 40.
22. Id. ¶ 45.
The first category, recombinant DNA techniques, makes the striking conclusion that recombinant DNA is different from “classical genetic techniques”\(^{24}\) in that new DNA techniques “permit the transfer of genetic material between widely divergent species; classical genetic techniques generally require considerable homology between the donor and recipient for genetic transfer to be possible.”\(^{25}\) However, this technology is not likely to result in an engineered weapon because “the resulting agents are unlikely to have advantages over known natural agents sufficient to provide compelling new motives for illegal production or military use in the foreseeable future.”\(^{26}\)

In the infectious disease category, the emergence of four diseases from 1967–1976 were significant\(^ {27}\) because they were agents that might be used in what was called “general acceptance that the most militarily efficient method of biological warfare is airborne attack by agent aerosols, discussion is restricted to consideration of such use”—Marburg disease, Ebola, Lassa fever, and Legionnaire’s disease.\(^ {28}\) The report concluded that no party was able to use any of these disease agents, there were existing agents that were already of such use, and the uncontrollability of these diseases was a negative factor in using them. Furthermore, the language of the BWC prohibited the use of each of these.\(^ {29}\) Finally, the major concern is for those diseases that are eradicated, like smallpox, because many countries have ceased vaccination for it, making it a potentially dangerous bioweapon.\(^ {30}\)

The third category, chemical synthesis of toxins, highlighted that the technological ability to synthesize toxins was theoretically possible, but the larger molecules posed problems. The prediction—“In time it will probably be possible to synthesize any toxin, no matter how large or complex”\(^ {31}\)—was accurate, and this capability was developed over the next two decades.

The fourth category, industrial use of fermentation techniques, was mainly concerned with manufacturing facilities that had the capacity to produce militarily significant quantities of biological products. The report cites to “a continual rapid expansion of the industry with an almost explosive increase in the availability of microbial products and the means of exploiting micro-organisms,”\(^ {32}\) also noting that this has occurred since the ratification of the 1975 treaty. These products include antibiotics, vaccines, enzymes, hormones, vitamins, amino-acids,
sugar substitutes, fertilizers, solvents, and fats for the chemical industry. The most significant technology noted was the “large-scale production of single-cell protein.”

The fifth category, microbial control of pests, focused on the trend toward substituting biological controls for pesticide controls of rodents and insects to avoid further environmental contamination. The research and use of these microbial pesticides and insecticides “[i]n some basic respects . . . resembles biological warfare,” making it a technology that has the potential to be used against humans. The examples used in the report include Bacillus thuringiensis, a bacteria used to kill pests. This is the same bacteria used in 1985, just five years later, to extract genes to insert in plants and make a pest-resistant tobacco plant.

The final category of the report, Scientific and Technological Findings, concluded that the BWC had not hindered the progress of the biological sciences “for peaceful purposes.” Further, they concluded, “[T]hese new agents are unlikely to improve upon known agents to the extent of providing compelling advantages for illegal production or military use in the foreseeable future.” However, particularly ominous is the prediction that “[s]cientific and technological developments have not created ambiguities or fundamentally new possibilities which could be exploited to violate covertly or bypass the Convention.” So the question remains whether this is still true today given the advances in scientific and technological biosciences.

Notably, the Soviet Union and the United Kingdom both made unequivocal official statements that they had never been involved with the manufacture of biological weapons. Only the United States had made a public statement about ending their biological weapons program, announced by President Richard Nixon in 1969. Later, it became evident that both the United Kingdom and the Soviet Union also had biological weapons programs before 1975. It is now widely known that the Soviet Union stepped up its biological weapons devel-

33. Id. at 16.
34. Id. at 14.
35. Id. at 15.
36. Id. at 17.
39. Id.
40. Id.
42. Id. at 16–17.
opment program after the signing of the BWC. The extent to which this joint report inspired or discouraged bioweapons development is not clear.

B. Second Review Conference (1986)

The First Review Conference had stipulated that they should meet again in 1986 but in no case later than 1990. This decision was based on the lack of a requirement in the BWC to have further review meetings after the first one. The Second Review Conference was scheduled and held in 1986. In April, the Preparatory Committee for the Second Review Conference asked the Depository Parties to submit “information on new scientific and technological developments relevant to the Convention.” The Committee invited States Parties “to communicate to the Secretary-General of the United Nations their views on new scientific and technological developments relevant to the Convention.” They further asked that that information be circulated two weeks before the conference in December 1986.

The Depository Parties and any other members were invited to submit their own reports on the scientific and technological advances since 1980, the year of the last report. The reports all concluded that the BWC still covered all potential risks including natural and synthetic agents. However, there were lengthy reports concerning the “biotechnology explosion” and the great increases in industrial-level capability in manufacturing large volumes of biologicals.

The report from the Soviet Union also concluded: “Analysis shows that the provisions of the existing Convention are broad and universal, and therefore extend to all micro-organisms and toxins of both natural and synthetic origin which could be regarded as agents for military use.” However, it was that twelve-page report that was ominous. Details of development advances in all areas addressed in the First Review Conference Report are striking. Other notable comments suggested that subverting investigation was possible, reporting in the toxins section that “[h]ybrid toxins are not more toxic than natural toxins, but it is possible to synthesize hybrid toxins which attack other organs and biosystems of warm-blood[ed] animals than those attacked

43. Id. at 17.
45. Id. at 1.
46. Id.
47. Id. at 12.
by natural toxins, and thereby distort the clinical pattern of poisoning.” 48 The same section describes the ability to manufacture large quantities of toxin, which was specifically found to be impracticable in the First Session Report. The Soviet Union’s report stated that “Saxitoxin has been produced at the rate of 0.5 grammes per month in a 4,000-litre bioreactor.” 49 Further, where there were four diseases outlined in the previous session’s report, the Soviet Union’s report added four new categories of viruses (Bunyaviruses, Flaviviruses, Togaviruses, and Arenaviruses), four new categories of bacteria (plague, tularemia, anthrax, and rickettsias), and a newly discovered agent (prions). They reported extensively on the U.S. Centers for Disease Control and Prevention’s discovery of AIDS in 1981 and its isolation in 1983. 50

The United Kingdom reported they would begin to use the term “genetic engineering” in place of “recombinant DNA techniques,” the term used in the First Review Conference Report. They noted there were no new diseases—in contrast to the Soviet Union’s lengthy coverage of the discovery of AIDS—and noted the discovery of prions. The United Kingdom also noted the “biotechnology explosion” and its related implications for abuse. They concluded with the following warnings: “Such developments in the civil sector are relevant to BWC and could be abused to support an offensive BW programme . . . . It is possible that technical developments since 1980 could, if abused, have relevance to the Convention.” 51

The United States reported great advances in manufacturing processes, rather than focusing on new categories of biological agents like the Soviet Union. The United States confirmed the capability of manufacturing large quantities of toxins as a significant advancement from 1980, 52 as did the Soviet Union. Although the pressure to develop an inspection protocol for verification of compliance with the treaty was mounting, the United States was opposed to exposing trade secrets and intellectual property of its biotechnology companies. In several references, the United States noted the increasing difficulty in verification given that “[d]evelopments intended to increase production, decrease cost and create safer conditions for handling biological materials have blurred former distinctions important for purposes of verification.” 53 Further, “[b]ecause of the large number of technical innovations in biotechnology, especially in the area of industrial microbiology, the BWC has become more difficult to verify since its

48. Id. at 11–12.
49. Id. at 11.
50. Id. at 10–11.
51. Id.
52. Id. at 3.
53. Id. at 4.
signature in 1972.”54 They add, “Verification of the Convention, always a difficult task, has been significantly complicated by the new technology. The confidence derived from the belief that certain technical problems would make biological weapons unattractive for the foreseeable future has eroded.”55 Yet the U.S. report concluded that they still believed Article I to be sufficiently comprehensive as to cover recent scientific and technological developments.56

Other parties made comments about the great advances in science and technology since the First Review Conference. The Netherlands was especially shrill about this observation reporting:

The Convention undoubtedly constituted a major step in the history of war and disease. Nevertheless, work must continue in order to keep the scientific and technological powers mankind had developed under control. Biological science and biotechnology had never moved as fast as in the years since the signing of the Convention and the pace of development was still not slowing down. The world could well be on the brink of a period marked by innovations in biotechnology. . . . At the First Review Conference, it had been agreed that the scope of the Convention was sufficiently broad to deal with new technological developments. Although that conclusion was still valid, the recent advances of biotechnology posed potential problems. Some Parties to the Convention might begin to believe that other Parties were in a position to develop new and effective biological weapons. Over the past six years, doubts had undoubtedly grown about compliance, doubts which had not yet been resolved.57

A repeated suggestion was that confidence-building measures involving disclosure of all facilities equipped to handle biocontainment levels were needed for these dangerous diseases.58

The documents evidenced significant discord. Most of the Second Review Conference focused on the Chemical Weapons Convention as a necessary next step. Iran was seeking condemnation of Iraq’s use of chemical weapons but did not get an official sanction. U.S. Ambassador Donald Lowitz made clear that he believed the BWC had been

54. Id.
55. Id. at 5–6
56. Id. at 5.
58. Id. ¶ 55.
violated. The Chinese Ambassador Fan Gaoxiang said the discussion had been “bitter” at times.

In the summary document setting out work to be done for the next conference, two significant tasks were assigned. The first was “the establishment of a group of scientific experts to study the latest biological developments of relevance to compliance with the Convention,” and the second was the “preparatory work for a special conference of the States Parties to the Convention to draw up and adopt an additional protocol which would provide for measures to strengthen the system of verification of compliance with the Convention.” The latter was significant because it would lead to the United States temporarily withdrawing from discussions.

Australian Ambassador Richard Butler expressed concerns that weapons could be engineered to target certain ethnic groups and that he did not believe the Convention covered that possibility. Butler also pointed out that the Soviet Union had an outbreak of anthrax among the people living in Sverdlovsk in 1979 and that the appropriate steps to investigate had never been taken. Butler also stated that toxins were used against resistance fighters in Laos and Cambodia and that investigations had been thwarted when the team of experts sent to investigate had not been allowed in the area.

Nigerian Ambassador Benson Tonwe stated that “[a]bove all, scientific and technological advances had outpaced the Convention.” Colombian Ambassador Héctor Charry Samper stated that “the new science of genetic engineering had been virtually non-existent in 1972. The advances since made in molecular biology had not been foreseen in 1972.”

Despite the assurances from the reports that BWC Article I still covered all possibilities of biological weapons, the parties affirmed that Article I was still sufficient to cover the new advances.

60. Id.
61. Id.
62. Id.
63. Id.
65. Id. ¶ 91.
C. Third Review Conference (1992)

The summary of the Third Review Conference specifically addressed additional understandings about Article I and added the following text:

The Conference notes the importance of Article I as the article which defines the scope of the Convention and reaffirms its support for the provisions of this Article.

The Conference reaffirms that the Convention prohibits the development, production, stockpiling, other acquisition or retention of microbial or other biological agents or toxins harmful to plants and animals, as well as humans, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, genetic engineering and biotechnology, and the possibilities of their use for purposes inconsistent with the objectives and provisions of the Convention, reaffirms that the undertaking given by the States parties in Article I applies to all such developments. The Conference also reaffirms that the Convention unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, whatever their origin or method of production.

The Conference notes that experimentation involving open-air release of pathogens or toxins harmful to man, animals or plants has no justification for prophylactic, protective or other peaceful purposes is inconsistent with the undertakings contained in Article I.66

D. Fourth Review Conference (1996)

The summary document added to Article I the additional understanding that “molecular biology . . . and any applications resulting from genome studies” was added to the list of technologies covered under Article I.67 The summary document also reaffirmed previous understandings since the First Review Conference.

E. Fifth Review Conference (2002)

The United States submitted a lengthy statement outlining scientific and technological advances. However, the final statement concluded:

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“The United States continues to believe that all of the scientific and technological developments described above are encompassed comprehensively under Article I of the BWC, which in turn places them within the purview of the Convention.”

The United Kingdom submitted an even lengthier statement, but it was unclear whether it believed Article I was still sufficient to cover the range of new advances in science and technology.

The United States and the United Kingdom were the only two depository parties to submit a statement on Article XII’s requirement to reassess the scientific and technological advances. The Conference focused more on confidence-building measures and the exchange of equipment.

F. Sixth Review Conference (2006)

The Sixth Review Conference reaffirmed “that Article I applies to all scientific and technological development in the life sciences and in other fields of science relevant to the Convention.” The summary document for the Sixth Review Conference compiled the additional understandings for the various articles, including Article I:

2. This document shows the text for each article of the Convention, followed by the additional understandings and agreements relating to that article reached by the various Review Conferences. For the purposes of this document, an “additional understanding or agreement” is one which:

(i) interprets, defines or elaborates the meaning or scope of a provision of the Convention; or

(ii) provides instructions, guidelines or recommendations on how a provision should be implemented.

Article I

Convention Text

“Each State Party to this Convention undertakes never in any circumstances to develop, produce stockpile or otherwise acquire or retain:


69. Id. at 9.

EMERGING BIOTECHNOLOGIES AND 1972 BWC

(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflicts.”

Additional Understandings and Agreements

5. The Third and Fourth Review Conferences reaffirmed that the Convention prohibits the development, production, stockpiling, other acquisition or retention or microbial or other biological agents or toxins harmful to plants and animals, as well as humans, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. [IV.I.2, III.I.2]

6. The Fourth Review Conference affirmed that the use by States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the Convention. [IV.I.3]

7. The Second Review Conference concluded that the scope of Article I covers scientific and technological developments relevant to the Convention. [III.I.2]

8. The Second, Third, and Fourth Review Conferences, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, genetic engineering and biotechnology, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirmed that the undertaking given by the States Parties in Article I applies to all such developments. The Fourth Review Conference supplemented the list of scientific and technological developments with molecular biology . . . and any applications resulting from genome studies. [IV.I.6, III.I.3, II.I.4]

9. The Second, Third, and Fourth Review Conferences reaffirmed that the Convention unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. The Second Review Conference added, consequently, toxins (both proteinaceous and non-proteinaceous) of a microbial, animal or vegetable nature and their synthetically produced analogous are covered. [IV.I.6, III.I.3, II.I.2]

10. The Third and Fourth Review Conferences noted that experimentation involving open-air release of pathogens or toxins harmful to man, animals or plants that has no justification for prophylactic, protective or other peaceful purposes is inconsistent with the undertakings contained in Article I. [IV.I.7, III.I.4]

11. The Third Review Conference stressed that States parties should take all necessary safety precautions to protect populations and the
environment in relation to activities not prohibited by the Convention. [III.1.5]

12. The Third and Fourth Review Conferences appealed through the States Parties to their scientific communities to lend their support only to activities that have justification for prophylactic, protective or other peaceful purposes, and refrains from undertaking or supporting activities which are in breach of the obligations deriving from provisions of the Convention. [IV.1.8, III.1.7]

This was the first “codification” of additional comments made to incorporate scientific and technological advances in a report from any of the Review Conferences. The result is that the definition in Article I still includes all of these advances.

G. Seventh Review Conference (2011)

The Seventh Review Conference reaffirmed the previous understanding of Article I and the scope based on scientific and technological advances. Most significantly, the decision was made to include a standing agenda item at the intercessional meetings between 2012–2015, leading up to the Eighth Review Conference in 2016.72

With regard to Article I, the Conference report stated, “The Conference reaffirms that Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention . . . .”73 The report also set forth a program of work in the Standing Agenda Item on the review of science and technology relevant to the Convention:

(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention; (b) new science and technology developments that have potential benefits for the Convention, including those of special relevance to disease surveillance, diagnosis and mitigation; (c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention; (d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry; (e) education and awareness-raising about risks and benefits of life sciences and biotechnology; (f) science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO,

71. Id. at 3–4.
73. Id. at 10.
EMERGING BIOTECHNOLOGIES AND 1972 BWC 711

IPPC and OPCW; (g) any other science and technology developments of relevance to the Convention.74

For each year, the work was set out in a topical way, leading up to the 2016 Eighth Review Conference.75 The topics and the years are as follows:

(a) advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology (to be considered in 2012); (b) advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants (to be considered in 2013); (c) advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues (to be considered in 2014); (d) advances in production, dispersal and delivery technologies of biological agents and toxins (to be considered in 2015).76

The work of the Convention has become much more complex with the rapidly increasing science and technology relevant to the Convention, and the topical work schedule, which focuses on advances in science and technology, makes this evident. It bears examining each of the conclusions from each of the available topical years to see how the scope of Article I of the BWC remains sufficiently broad to cover realities.

The preparatory meetings cover an increasingly diverse and broad compendium of new discoveries and technologies that are relevant to the Convention.77 The increasingly complex equipment may be an impediment to smaller-scale attempts to use bioweapons, but it is clear it could be a pathway for governments that might invest in these major dual-use technologies.78 The Report of the 2014 Experts Meeting is the most striking report that the world has ever seen to date on

74. Id. at 23.
75. Id.
76. Id. at 23–24.
78. See Implementation Support Unit 1, supra note 77, at ¶ 40.
the vast amount of knowledge and its digital management, making it accessible and useable. 79

The science and technology advances first mentioned in 2014 were in a section titled “Characterizing biological systems and networks,” a different category than prior reports.80 Among those mentioned was the ability to create novel life forms by substituting base pairs in DNA with unnatural substitutes,81 the creation of genetically modified mammals using the CRISPR-Cas9 system,82 a type of gene-circuitry engineering, and genetically modified mosquitoes for controlling proliferation.83 For the first time, threats such as these broaden the Article I description of “microbial or other biological agents or toxins”84 to an assigned meaning that no longer matches the plain meaning of the treaty, taking in mammals and insects.

III. THE SCOPE OF THE ARTICLE I DEFINITION

Part II shows deliberations since the signing of the treaty to determine if the BWC definition for biological weapons is still sufficiently broad to encompass all the identified new technologies as the current state-of-the-art as long as the continuing review adds these additional understandings to the Convention record. This has required the Meetings of Experts to increasingly broaden the scope of the definition with each meeting.

In the first two review conferences, confidence was high that nothing new was beyond the scope of the treaty. However, subsequent review conferences (Third, Fourth, and Fifth) became increasingly urgent because these advances in science and technology were presenting dangerous risks if misused. The most recent review conferences (Sixth and Seventh) made lists of new technologies so lengthy that more categories for addressing them were required just to track the


82. Id. ¶ 30.

83. Id. ¶ 31.

84. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, supra note 5, art. I.
A new category of technologies that are helpful for surveillance and detection was also added. While there were increasing demands from countries other than the Depository Parties seeking verification protocol and confidence-building measures were evident in the comments, doubts about the stewardship or the sharing of these technologies under Article X, were also evident. In many ways, the explosion in new life sciences technologies has driven the countries without them to become more vocal about their concerns.

The Seventh Review Conference introduced new confidence-building measures forms, unlike the previous guidance, that required disclosures with far more detail than ever before. One of the forms requires an inventory of the countries’ biological containment laboratories and the biosafety level of each of them and what they contain. More than once, and before a Congressional hearing, the U.S. Centers for Disease Control and Prevention has declared that it is unknown how many or where all the biological containment laboratories are in the United States and that, because there is no regulation that requires such disclosures, no regulatory agency is tracking this data unless the laboratory is involved in a federally funded contract. Russia has never made such a disclosure. This may be why they refused to accede to the final report of the Seventh Review Conference, submitting an official statement February 17, 2015, that concludes: “[T]he Russian Federation considers paragraphs 19 through 59 of the above


86. Id. ¶ 68–69.


document [Final Report, 1-5 Dec. 2014] as having no approved status, and, therefore, no commitments may arise from therein.”90 This could prove to be a possible diplomatic challenge at the Eighth Review Conference when the geopolitical rotating chair will go to the Eastern European region of which Russia is a major member.

In the final Report of the Experts in August 2014,91 the new technology, synthetic biology, was mentioned for the first time during this year leading up to the Eighth Review Conference. Tracking the focus on this term, it was mentioned in fourteen of the seventy-nine pages dedicated to advances in technologies, and it was mentioned a total of twelve times by eight countries. Pakistan, Nepal, and Russia mentioned synthetic biology in negative statements.92 Iran mentioned synthetic biology both in positive and negative statements.93 Sweden, Canada, and the United States all made positive statements about synthetic biology. Russia’s comments were the most extreme, stating that synthetic biology posed “dangers . . . comparable to that of nuclear hazards,” and that “the expert community acknowledges that these risks are exceptionally high.”94 Pakistan commented that “[t]he recent advances in synthetic biology raise immediate concerns.”95 Sweden referred to “the era of synthetic biology.”96 Overall, the positive comments tend to be about the promise for developing drugs and vaccines.97 Canada was the only country to mention the iGEM Competition, synthetic biology in the context of a strictly rule-bound competition, saying, “iGEM promotes responsible, safe, and ethical use of synthetic biology.”98 The United States only mentioned synthetic biology in a list of examples of “fast-moving” fields and the need to establish an expert committee to keep track of these advances in science and technology.99 The Convention determined synthetic bi-

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92. Id. at 22–32.
93. Id. at 25–31.
94. Id. at 32.
95. Id. at 22.
96. Id. at 31–32.
97. Id. at 22–37.
98. Id. at 35.
99. Id. at 37.
EMERGING BIOTECHNOLOGIES AND 1972 BWC

ology relevant and understood it as encompassed by the Article I definition.100

The website quotes from the report in summary: “The Seventh Review Conference reaffirmed that ‘Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention.’”101

IV. COULD THESE ALSO BE CONSIDERED WITHIN THE SCOPE OF THE BWC?

A. Invasive Species

The understandings from the Review Conferences have extended the Article I definition to include genetically modified mammals as well as genetically modified insects.102 So the definition in Article I, which begins with “microbial and other biological agents,” does not create a restriction on the size of the threat.103 Then, would invasive species that can be devastating and costly to a nation be included in this definition? Because there is no other treaty that covers this threat, is it more “related to” the BWC?

The enforcement, verification, and transparency around the use of invasive species as a biological weapon would be an entirely different kind than the dual-use science and technologies that are central to the discussion of the definition. Invasive species would likely have no dual use, yet the conversation surrounds only dual-use technologies. Would that then be a requirement of this Article I understanding? There is nothing to suggest it should be, but that is the practice throughout all of the review conferences after the First and Second.

Invasive species, in fact, would be the crudest of biological weapons that could infest a water supply (zebra mussel),104 infest a town, or be a threat to the safety of entire regions or countries (Brown Snake of Guam).105 Given the scope of the understandings, this would arguably be swept into the Article I definition.

100. Id.
102. See supra notes 80–84 and accompanying text.
103. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, supra note 5, art. I.
B. Nanobiotechnologies

Bionanotechnologies or nanobiotechnologies both involve the interdisciplinary combination of nano-size materials in the field of biology.\(^\text{106}\) Nano size is one billionth of a meter.\(^\text{107}\) In addition to the obvious size difference, materials this small can change in surface charge, color, and other properties, which can be useful. The ability to manipulate materials of this size gave rise to exploring many interdisciplinary applications including biology.\(^\text{108}\) The intersection of biology and nanotechnology is one of the fastest areas of growth in nanotechnologies.

The possibility of nanotechnologies escaping notice under the BWC is very real where the small size is invisible to the naked eye and materials can go undetected—much like disease agents. Furthermore, if they are designed to be inhaled or absorbed into skin, they can go undetected. Nanobiotechnologies might enter the body by pathways very similar to disease, making them potential biothreats if they cause harm, inoculate the inhaler with anything harmful. If these components had no biological component, they would not fit the current definition of a “microbial or biological agent.”

The term nanotechnologies was mentioned for the first time in the 2014 Meeting of the Experts and was mentioned only twice—once by Iran\(^\text{109}\) and once by OPCW\(^\text{110}\)—both in a positive manner.

C. Biotechnology Weapons (Physiological and Psychological Substances)

A new class of military biotechnology could also evade regulation under the BWC but may be part of the inventory of “other scientific advancements,” a category included in the Article XII review in the Seventh Review Conference. One author defines modern military biotechnology as “biotechnology applied to the military domain to produce weapons-like effects [and it] is fundamentally different from traditional biological weapons. The confusion of the two concepts is not scientific and is not helpful to the proper development of military

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106. EHUD GAZIT AND ANNA MITRAKI, PLENTY OF ROOM FOR BIOLOGY AT THE BOTTOM: AN INTRODUCTION TO BIONANOTECHNOLOGY 1 (2013).
110. Id. at 27.
biotechnology of the final elimination of traditional biological weapons.”111

Examples of these types of weapons-like materials include using biomolecule functions to modify living tissues according to precise procedures and conditions and to modify cell functions. “In the final analysis, war is simply human behavior that forces enemies to lose the power of resistance.”112 Another example is a military attack to damage “genes, proteins, cells, tissues, organs,” causing more damage than conventional weapons,” but it is not uncontrollable like disease agents.113 Another is similar to a latent computer virus injected at some time in a human body and activated by some causative agent.114 The author cites to the ability to destroy food and water resources and current rubber-destroying compounds. On the other hand, the author suggests that a viral vector as a delivery device would not be a biological weapon.115 Perhaps most frightening is the “direct integration” approach, which would utilize a particle gun to create a microbullet out of a 1-micrometer tungsten or gold ion, on whose surface plasmid DNA or naked DNA could be precipitated, and deliver the bullet via a gunpowder explosion, electron transmission or high-pressured gas to penetrate the body surface. We could then release DNA molecules to integrate with the host’s cells through blood circulation and cause disease or injury by controlling genes.116

The author also refers to the “superiority of biotechnology weapons” in that they are so much more precise and undetectable that their use will do away with all threat of traditional “primitive” biological weapons.117 This may be a case where the cure is worse than the disease.

Another possible category of biologics are those solicited by the Special Forces in the publicly available document by the Future Technology Working Group in 1999 that “identifies the military appeal of ‘a bio-engineered organism [that] can become a weapon by acting as a corrosive agent after a certain period of time or by a remote command.’”118 "The document “sets out the uses of a 'bio-organism that can be placed on a building and then grow across that building to act as an illuminator for target identification, or precision attacks’ (tag-

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112. Id. at 76.
113. Id. at 76–78.
114. Id.
115. Id. at 76–77.
116. Id. at 77.
117. Id. at 78.
It also “indicates that these bioweapons would be used covertly, stipulating that they ‘should be innocuous in appearance so that they can be carried and placed by Special Operations Forces without detection.'”

These applications may not have dual uses and thereby escape the attention of the updates in scientific and technological advances “relative to” the BWC. The possible use of any biological material, such as these, should be included in the broad understand of the Article I definition.

V. CONCLUSION

By having the Standing Agenda Item for review of developments in science and technology advances “related to the Convention,” it is a foregone conclusion—a self-fulfilling prophecy—that all of the technologies by definition will be those that fit within the scope of Article I. The scope of the definition has become so broad that the plain meaning of the definition is no longer evident that these threats are covered, and reliance on the Convention interpretation and additional understandings is essential for the Convention to be relevant to current technologies not in existence at the time it was drafted in 1972.

With the inclusion of everything identified in these reports as coming within the scope of the Convention, there are clearly security threats that may not be “relevant.” Thus, they will be overlooked, and hazards that may escape notice of international attention could very well be looming as the next global security threat. Not only is the scope of the treaty increasingly broad, there are even more threats and future technologies potentially on the horizon that will make it more and more difficult for this patching mechanism to ensure the safety of the world from the increasingly available biotechnologies.

President Nixon announced the end of the U.S. biological weapons program in 1969, adding, “Mankind already carries in its own hands too many of the seeds of its own destruction. By the examples we set today, we hope to contribute to an atmosphere of peace and understanding between all nations.”

The exercise of defining what is a biological weapon under Article I may be a patchwork that can only protect us for so long; another approach to avoiding our own self-destruction should be explored.

119. Id.
120. Id.